

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	
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THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
01-CV-12257-PBS AND 01-CV-339	)	Chief Magistrate Judge Marianne B. Bowler
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**DIRECT TESTIMONY OF RAYMOND S. HARTMAN**

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#### ATTACHMENTS

- A. CURRICULUM VITAE
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## I. INTRODUCTION AND OVERVIEW

1. My name is Raymond S. Hartman. Since I have presented my qualifications to this Court in this and other recent matters, I do not reiterate them here. I do however attach, in Attachment A, my current curriculum vitae and a current listing of testimony and/or appearances at deposition or trial. Attachment B is a listing of materials relied upon.

2. I have been asked by Counsel to determine, using standard economic methodologies and the data which are sufficient for implementing such methodologies, the aggregate overpayment incurred by Class 2 and Class 3, as defined by Judge Saris,<sup>1</sup> for specific drugs during the Class Period due to the alleged wrongful conduct of Defendants. In doing so, I have been asked to determine causation and liability, by drug and by Defendant, for Class 3. As a matter of economics, quantitative analysis and common pharmaceutical business practices, I conclude that liability can be so determined on a class-wide basis for Class 3, and that aggregate Class-wide damages can be calculated accurately and reliably using standard formulaic methodologies for both Classes. In Sections IV, VI and VII, I discuss and implement the methodologies I use to calculate the aggregate damages to Class 2 and Class 3 attributable to each of the remaining four Track One Defendants.

3. For Class 2, I have been asked by Counsel to assume that AWP is defined by the Court as a statutory matter to mean a published price that is an “average of wholesale prices.” For the purpose of my testimony I take this interpretation to mean that the “average of wholesale prices” was plainly intended to reflect the average acquisition cost of providers at wholesale,

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<sup>1</sup> *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Memorandum and Order re: Motion for Class Certification, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, August 16, 2005 (hereafter, *Memorandum and Order*), p. 87.

with some nuances developed in detail with the damage calculations below. I have also been asked by Counsel to assume for purposes of Class 2 that price data furnished by pharmaceutical manufacturers to determine reimbursements must take account of price reductions, cash discounts, rebates, free or reduced price services (where appropriate) and other discounts referred to in the OIG Compliance Program Guidance for Pharmaceutical Manufacturers.<sup>2</sup> I note in passing that this OIG Compliance Program Guidance (hereafter *Compliance Program Guidance*) is generally consistent with the offsets required for calculating ASPs under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MPDIMA).<sup>3</sup>

Taking these instructions as a point of departure, I have calculated the spread between the published AWP for each NDC and what should have been provided as the basis for pharmaceutical reimbursement (ASP) to providers. I have done so using data produced by each Track 1 Defendant remaining in the litigation. From these data, I have calculated spreads and what I will call statutory damages to Class 2.

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<sup>2</sup> Department of Health and Human Services, Office of Inspector General, Federal Register, Vol. 68, No. 86, 23731-23743 at 23733-34, (May 5, 2003).

<sup>3</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, December 8, 2003.

The language presented by the OIG and in MPDIMA is generally consistent in their specification of how manufacturer's prices are to be reported.

According to the MPDIMA, Federal Register, Vol. 69, No. 4, Wednesday, January 7, 2004, Page 1091: "In the calculation of the manufacturers' average sales price, a manufacturer should include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under the Medicaid program)."

According to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, page 12 and Department of Health and Human Services, Office of Inspector General, Federal Register, Vol. 68, No. 86, 23731-23743 at 23733-34: "Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues)."

4. I have been asked as an economist to analyze the behavior of each of the Defendants to determine what incentives existed for them to publish inflated AWPs for Medicare Part B reimbursable single-source drugs and in the case of Medicare Part B reimbursable generics to support an inflated median AWP while secretly lowering the acquisition cost to providers. I have concluded that such incentives did exist and that each Defendant engaged in tactics designed to aid sales of their drug(s) by increasing the spread between the published AWP and the provider acquisition cost, thereby using spread as a profit center for providers.

5. For Class 3, I have also considered the use of AWP as a reimbursement benchmark in the private pharmaceutical-reimbursement marketplace for the same prescription drugs and have concluded that AWP was and is a recognized industry benchmark and was utilized by members of Class 3 as a basis for reimbursement of the drugs at issue in this litigation. Literature, Defendants' own documents, Defendants' experts, the Report of Professor Berndt, third-party payor deposition testimony, and analysis of contracts and actual reimbursement data confirm this. This Court has recognized industry reliance upon the AWP benchmark.<sup>4</sup> As a matter of basic economics, rational participants in an economic transaction would not willingly adopt a benchmark that they knew was artificially and grossly inflated or led

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<sup>4</sup> In her *Memorandum and Order*, Judge Saris recognizes reimbursement reliance upon AWP as follows:

- “Throughout the class period, from 1991 to the present, AWP has been the pricing benchmark for most pharmaceutical sales in the United States” (p. 7).
- “In almost every sale of prescription drugs, reimbursement from the government or TPP is based on AWP, WAC, or a discount from one of these numbers (e.g., AWP minus 15%)” (p. 9).
- “First, physician-administered drugs (mostly brand-name drugs) are generally sold to consumer-patients by physicians, who are reimbursed by the government Medicare Part B program and by private sector TPPs. Consumer-patients typically make “co-insurance” payments for these drugs, meaning they pay a portion of the cost of the drug based on a percentage of AWP, rather than a flat co-payment” (p. 12).
- “AWP was the basis for drug reimbursement under Medicare Part B for most of the proposed class period” (p. 14).

to arbitrary prices of goods and services they were purchasing. Based upon my experience in studying, writing about, and analyzing pricing in this industry and using standard economic methodologies and data, I have determined that certain drugs were priced at levels not reasonably related to acquisition cost and/or exceeded the expectations as to the difference between a published AWP and provider acquisition cost. Having determined which drugs exceeded these expectations, I have calculated aggregate damages for Class 3.

6. I have also examined the issue of market knowledge, *i.e.*, is there quantitative economic evidence that members of Class 3 knew of Defendants' *systematic* abuse of the AWP-based system for reimbursement of Medicare Part B drugs through large and arbitrary spreads between AWP and acquisition cost and through the tactics being used by Defendants to utilize the spread as a promotional sales tool? I find no evidence of such knowledge in deposition testimony of the relevant Class-member TPPs. I find no publicly-available evidence sufficient to inform Class-member TPPs. The available economic data, consisting of published survey research and negotiated contracts, indicate to me that spreads were generally believed to be in a range that supported negotiated reimbursement rates of  $AWP \pm 15\%$  in contracts and  $AWP - x\%$  for single-source physician-administered drugs in the survey research, where generally  $x\%$  was at most 20%. I find, as does Dr. Berndt, that publicly-available market information concerning the spreads for multi-source physician-administered drugs were sufficiently idiosyncratic or limited so as to be insufficient for market participants to draw any conclusions regarding Defendants' *systematic* abuse of the AWP system through spreads for Defendants' multi-source drugs. I find that actual spreads were often far in excess of the spreads that could be deduced from available market information and that the measures I use to characterize overall market expectations are conservative.

## **II. THE MEDICARE PART B PROGRAM AND ITS RELIANCE ON AWP FOR COST-BASED REIMBURSEMENT**

7. Class 2 reimbursement is wholly dependent upon the Medicare payment system for Part B drugs. I have researched the history of that payment scheme and discuss it below as background for clarifying the financial incentives at the heart of the AWP Scheme. Such research into the regulatory and statutory background of an industry is common for economists analyzing that industry and its competitive landscape. It is certainly a prerequisite for any economist rendering opinions about the markets at issue here, since conduct and pricing in these markets diverge importantly from the competitive paradigm. Consequently, incorrect application of simple competitive theories can produce inappropriate and incorrect conclusions.

8. The Medicare program was established in 1965 as an amendment to the Social Security Program. Medicare provides health insurance to persons age 65 and older, to qualifying persons under 65 with certain disabilities and to persons of any age suffering from permanent kidney failure. Medicare is the nation's largest health insurance program, covering over 39 million people in 2003. Through 2005 it was composed of three parts: a Hospital Insurance Program (Part A), the Supplementary Medical Insurance Program (Part B), and a managed care program (Part C, once called "Medicare Plus Choice" and now called "Medicare Advantage") that offers enrollees the opportunity to join a commercial health plan instead of receiving coverage through Parts A and B.<sup>5</sup> Part B, which primarily covers physician services, is optional. Most Medicare beneficiaries choose to enroll in Part B and either pay the premium themselves or have it covered by a former employer or Medicaid. Medicare coverage is generally subject to a

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<sup>5</sup> For Part C insureds, the private health plan takes the risk for all reimbursement, including physician-administered drugs. To the extent Part C insureds appear in my analysis, they appear in Class 3. Part D is the self-administered prescription drug benefit that took effect on January 1, 2006. The implementation of Part D has occurred beyond the period for which I have data, and I do not analyze it.

deductible and a 20 percent coinsurance requirement. In addition, many Medicare beneficiaries also purchase private supplemental coverage to pay for Part B cost sharing. Some employers offer supplemental coverage to their retirees and certain low-income Medicare beneficiaries qualify to receive Medicaid coverage for their cost sharing.

9. Medicare was modeled on the major medical plans then popular in the private sector. The private plans were primarily intended to cover catastrophic health care costs with substantial cost sharing at the front end (*i.e.*, deductibles and coinsurance). Like most employer-sponsored plans in 1965, Medicare did not offer routine coverage for outpatient prescription drugs. However, a small group of specialty drugs was and continues to be covered under Medicare Part B. These drugs typically are administered by physicians in the office setting or in hospital outpatient departments, although some self-administered drugs are also covered.

10. Reimbursement for prescription drugs under Part B in the Medicare program has been based on the Average Wholesale Price (AWP)<sup>6</sup> reported by drug manufacturers and published in the standard directories (Red Book, First Databank (Blue Book) and Medispan). While the precise formula for AWP-based reimbursement has changed over time, reliance on AWP was a constant until January 1, 2005, when the reimbursement basis was changed to 106%\*ASP by the Medicare Prescription Drug Improvement and Modernization Act of 2003.

11. More specifically, the Social Security Act Amendments of 1965 (P.L. 89-97) explicitly link reimbursement to cost as follows:

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<sup>6</sup> “Apparently from the beginning of the program, Medicare has based payment for drugs on published ‘average wholesale price’ (AWP). AWP is used throughout public and private insurance programs as the basis for drug reimbursement, both for drugs administered in physician offices and for drugs dispensed by pharmacies. The amount of reimbursement varies from plan to plan and setting to setting, but it is almost always expressed as a percentage of AWP.” American Society of Clinical Oncology (ASCO), “Reform of the Medicare Payment Methods for Cancer Chemotherapy,” May 2001, p. 5.

“The amount paid to any provider of services with respect to services for which payment may be made ... shall ... be the reasonable cost of such services...”<sup>7</sup>

12. I understand that the original intent of Congress was to pay a reasonable amount to providers for the care of Medicare patients.<sup>8</sup> In a 1995 article, Robert Ball, who served as commissioner of Social Security under Presidents Kennedy, Johnson, and Nixon, provides an insider’s insights concerning the intentions of Medicare legislators.<sup>9</sup> In connection with all hospital care, he states that:

“By and large, our posture at the beginning was one of paying full costs and not intervening very much in how hospitals, at least the better ones, conduct their business ... We believed in paying fully. We opposed shifting costs to other payers, and we avoided discounts beyond what our contractors might have secured for their own insured persons.”

In connection with out-patient physician services, he states that:

“Reimbursement was to be a ‘reasonable’ charge determined by the customary charges of the particular physician and the prevailing charges in the locality for similar services.”

13. Reliance upon cost-based measures for reimbursement (for physician services under Part B) was further formalized in the early 1990s by the Centers for Medicare and Medicaid Services (CMS) through research undertaken to develop resource-based relative-value scales (RBRVS). RBRVS were developed in cooperation with representatives of the American Medical Association to provide methods of determining amounts to reimburse physicians under Part B for the thousands of provider procedures performed as summarized by CPT codes. CMS

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<sup>7</sup> In connection with hospital inpatient expenses, see § 1814 (b) of the Social Security Act Amendments of 1965 (“Medicare”). In connection to supplementary benefits of the Act, it is stated in Part B § 1833 (a) that “... there shall be paid ... [for] each individual who is covered ... amounts equal to ... 80 percent of the reasonable charges ...”

<sup>8</sup> Donald F. Beck, *Principles of Reimbursement in Health Care*, Aspen Publication, Rockville, MD, 1984, p. 3.

<sup>9</sup> Robert M. Ball, “What Medicare’s Architects Had in Mind,” *Health Affairs*, 14(4), 1995, pp. 62-72. The specific quotes that follow in this paragraph are found on pp. 68-69.

maintains and modifies over time the RBRVS, thereby allowing for the alteration of reimbursement amounts in light of changes in relative and overall medical costs and the relative value of the particular procedure. As a result of Medicare's reliance upon a RBRVS, reimbursement amounts *are designed to be and expected to be related in a predictable way to costs*, a predictable way that can be translated into yardsticks. I explain the economic basis of the CMS RBRVS in more detail in Attachment C to this Declaration, and its relationship to yardsticks for the reimbursement of physician services and drugs under Part B.<sup>10</sup>

14. The cost-based reimbursement procedures used by Medicare carriers prior to January 1, 1998 to determine the amount allowed as reimbursement for a covered drug were based on the lower of the Estimated Acquisition Cost (EAC) or 100% of the national AWP for that drug. The EAC, and its concordance with AWP, was to be determined based on surveys of actual invoice prices paid for the drug and thus designed to represent the actual cost (or "usual and customary charges") of drugs for direct purchasers (the providers, in the case of Medicare Part B).

15. Historically, however, Medicare carriers did not conduct such surveys and, instead, based reimbursement on reported AWPs,<sup>11</sup> despite the fact that Congress intermittently has revisited the need for such studies.<sup>12</sup>

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<sup>10</sup> In Attachment C, I demonstrate that the CMS RBRVS system is designed to provide the economic foundation for provision of medically appropriate provider services. I demonstrate that it would be economically irrational for TPPs reimbursing under Medicare to rely upon a reimbursement system that did not yield reasonable relative values such as does the RBRVS. Finally, I demonstrate that the CMS RBRVS reimbursement system is a natural descriptor of the yardstick methodology required and implemented in my liability and damage analysis for Class 3.

<sup>11</sup> See "Excessive Medicare Payments for Prescription Drugs," Office of Inspector General, Department of Health and Human Services, December 1997, OEI-03-97-00290, p. 1.

<sup>12</sup> The Benefits Improvement and Protection Act (BIPA) of 2000 recognized in passing that more studies were needed to determine "the average prices at which ... drugs ... are acquired by physicians and other suppliers."

This reliance upon reported AWPs in the absence of surveys is understandable given the “information” available through AWP-price-reporting services in the market and the administrative efficiency of using that information. The underlying belief that those reported AWPs were “provider-cost-based measures” for Medicare was buttressed by the assertions of the publishers themselves. For example, the promotional materials for First DataBank (FDB), the single most important provider of electronically integratable drug price information during much of the Class Period<sup>13</sup> asserted the following:

“I have had many conversations regarding what ‘AWP’ is and how First Data determines it. There is much folklore and misunderstanding as to the determination of AWP and how we obtain the data.

AWP is the average wholesale price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is *average*. AWP was developed to provide a price, which all parties could agree upon.

In order to determine the AWP, First DataBank surveys national wholesalers to ascertain what they use as a price basis in their AWP price files. We contact the wholesalers to determine what the markup should be for a new company or to confirm that the markup we are applying is current. A survey may be performed on a single NDC number or on a manufacturer’s entire product line. In either case, each national wholesaler is surveyed on a number of products from each manufacturer.

The number of surveys is increasing. First DataBank surveys drug wholesalers that represent over two-thirds of the wholesaler total dollar volume. The markup that First DataBank utilizes is representative of wholesalers on a national level. Because individual wholesalers may mark up each manufacturer differently, a weighted average, not a consensus average, is calculated. That is, the market share held by the wholesalers surveyed affects the markup factor proportionally. Wholesalers with higher drug dollar volumes have more weight in the

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<sup>13</sup> The FTC found that FDB had a monopoly on the market for integrateable electronic price data bases reporting AWP and WAC during the period 1998 through FTC’s forced divestiture of MediSpan by FDB in late 2001. (See Complaint for Permanent Injunction and Other Equitable Relief Pursuant to Section 7A(g)(2) of the Clayton Act and Section 13(b) of the Federal Trade Commission Act, *Federal Trade Commission v. The Hearst Trust, The Hearst Corporation and First Databank, Inc.*, United States District Court for the District of Columbia, Civ. No. 1:01CV00734.) However, I understand that a data sharing agreement between FDB and MediSpan continued FDB’s monopoly provision of integrateable electronic AWP price data until October 2004.

determination of the final markup. Thus, a higher degree of certainty is achieved (*emphasis in original*).<sup>14</sup>

16. On January 1, 1998, 42 C.F.R. § 405.517 was amended so that the allowed amount would be based on the lower of the billed charge on the Medicare claim form or 95% of AWP. In practice, the notion of the “billed charge” was the acquisition cost of the drug to the provider.<sup>15</sup> In practice, reimbursement has been paid using 95% of the AWP.

17. On January 1, 2003, the CMS implemented a “Single Drug Pricer” (SDP) policy that created a uniform system of prices for drugs covered by Medicare Part B based on 95% of AWP, continuing the Medicare drug-pricing system’s reliance on AWP.<sup>16</sup> At the same time, CMS authorized its carriers (the Medicare Payment Safeguard Administrators, MPSAs) to pay

<sup>14</sup> Cited at ¶ 78 of the February 9, 2005 Independent Report of Dr. Berndt. See also *New England Carpenters Health Benefits Fund; Pirelli Armstrong Retiree Medical Benefits Trust; Teamsters Health & Welfare Fund of Philadelphia and Vicinity; and Philadelphia Federation of Teachers Health and Welfare Fund v. First Databank, Inc., and McKesson Corporation*, United States District Court District of Massachusetts, C.A. No. 1:05-CV-11148-PBS, “Average Wholesale Price,” FDB-AWP 02023 and “PriceAlert, The Official Guide to AWP Pricing,” 3/15/2000, FDB-AW 15102-4. When marketing its products, FDB made it known that its AWP was the market standard, stating it “provides you the same AWP prices used by Aetna, PAID PCS, MEDI, MET, most Blue Cross Blue Shield Plans, wholesalers and approximately 49 Medicaid programs” (FTC Complaint, *op. cit.*, ¶ 103). As we know now, this characterization of AWP is wrong. However, it is clear that much of the industry relied upon such promotional claims in the past. Indeed, even Defendant manufacturers believed these surveys were being undertaken; see footnote 146.

<sup>15</sup> I base this assertion on the following fact discovery and testimony.

- CMS statements. For example, in his March 21, 2002 testimony to the U.S. House Energy and Commerce Subcommittees on Oversight & Investigations and Health on Part B drug reimbursement, Thomas Scully, CMS Administrator, states “These drugs are typically provided in the hospital outpatient setting, dialysis centers, or in the doctor’s office, and are purchased directly by the physician or provider. … By law, we generally pay for these drugs based on the actual charge or 95 percent of the AWP, whichever is lower.” He confirms this position in similar testimony to the Senate Finance Committee Subcommittee on Health, March 14, 2002.
- The alternative reimbursement basis before 1998 was EAC. The alternative basis returned to EAC (ASP) in 2005.
- This understanding is reflected in Defendants’ expert Steven Young testimony: “From 1992 to date, moreover, reimbursement under Medicare Part B has generally been made at the lower of the billed charge amount or AWP (through 1997) or 95% of AWP (after 1997). The Carriers may reimburse at less than the AWP based rates where, for instance, the physicians’ billed charges are less” (Young October 25, 2004 Rebuttal Declaration at ¶ 170).

<sup>16</sup> Centers for Medicare & Medicaid Services, “Single Drug Pricer (SDP),” Program Memorandum: AB-02-174, December 3, 2002.

for certain drugs based on the price (AWP) of the “least costly alternative” (LCA).<sup>17</sup> While the LCA has been used selectively since 1997, its use has certainly not become universal for all Medicare carriers and all groups of therapeutic substitutes.<sup>18</sup>

18. The Congress further revised Part B drug reimbursement in the Medicare Prescription Drug Improvement and Modernization Act of 2003 (hereafter, *MPDIMA*). Over the period since Medicare’s inception and most importantly during the 1990s, the relevant Medicare agencies (HCFA, CMS) were presented with increasingly compelling and consistent information sufficient to make clear that while AWP historically may have reflected provider acquisition cost, and while the AWP continued to be described by the major integratable electronic price data source (FDB) as the “weighted average wholesale price” (see ¶ 15 above), AWP was no longer the reliable benchmark it had been and had been believed to be. Rather, the AWP system had proven to be subject to such extensive abuse that an alternative method of cost

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<sup>17</sup> Medicare Carriers Manual, § 2100.2(B). Least Costly Alternative (LCA) requires that a local Medicare carrier not cover the additional cost of a more expensive product if a clinically comparable product costs less. Therefore in states where a carrier applies the LCA policy, physicians that administer the more expensive drug will be reimbursed at an amount related to the AWP of the less expensive drug. Carriers’ use of LCA is supported by CMS in its Program Integrity Manual (Chapter 13, Section 5.4), as quoted in “Medicare Reimbursement for Lupron,” Office of Inspector General, Department of Health and Human Services, January 2004, OEI-03-03-00250:

“Least costly alternative is a national policy provision that must be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principal to payment for non-DME services as well” (p. 2).

LCA, first implemented for Lupron in South Carolina in 1997, has determined Part B reimbursement for Lupron and Zoladex – both GnRH agonists used in the treatment of advanced prostate cancer. The drugs are clinically comparable; therefore, the carriers will only reimburse up to the allowable reimbursement rate (AWP-based) for Zoladex, the cheaper of the two drugs. Any physician who administers Lupron to a Medicare patient only receives the allowable AWP-based reimbursement rate for Zoladex. As of January 2004, Medicare carriers in 47 of 57 jurisdictions apply a least costly alternative policy for Lupron; see “Medicare Reimbursement for Lupron,” *op. cit.*, p. 5.

<sup>18</sup> A recent attempt by Medicare insurance carriers in Florida, Illinois, Indiana, Kentucky, Louisiana, Ohio, Pennsylvania, South Carolina, and Texas to implement an LCA policy for Zemplar, an intravenous drug prescribed for dialysis patients, was being challenged as of 2002 and had failed in Florida. See Maureen Michael, “Is the Medicare Policy in Several States to Restrict Access to Vitamin D For Dialysis Patients Heading in the Wrong Direction?,” Focus on Nutrition: Opinion, Contemporary Dialysis & Nephrology, <http://www.ikidney.com/iKidney/InfoCenter/Library/CDN/Archive/VitaminD0802.htm>, accessed August 6, 2004.

reimbursement was believed appropriate. The *MPDIMA* recognized this fact and the desirability of returning reimbursement to a measure of costs less susceptible to manipulation – the calculated, average sales price to the providers. Specifically, the basis for drug reimbursement was changed to 106% of the “Average Sales Price” (ASP), rather than the former 95%-of-AWP standard. For the year 2004, while transitioning from AWP to ASP, the basis for drug reimbursement was set at 85% of AWP, with some variation for particular drugs and biologicals.<sup>19</sup>

### **III. THE ECONOMIC INCENTIVES OF DEFENDANTS TO UNDETAKE THE AWP SCHEME**

#### **A. Overview – Spread Competition through AWP Inflation**

19. The alleged fraud was possible in this case because of three simple facts and one observation developed in Section II above. Fact 1 is that Medicare reimbursement generally and for Part B drugs specifically was originally and formally designed to be cost-based and was believed by payors to be cost-based for a long period of time. Fact 2 is that CMS believed that AWPs were administratively efficient and sufficiently reliable indicators of relative costs to meet the requirements of a relative value scale reimbursement system (see ¶ 13 above and Attachment C). Fact 3 is that CMS rationally exhibited inertia with respect to the incrementally accumulating information on diverging spreads between AWP and provider acquisition costs (as I develop in Section V below). Until the statutory changes enacted in 2003, CMS found the accumulating information incomplete and not sufficiently systematic to warrant entirely revamping its AWP-based reimbursement practices and procedures. The one observation is that

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<sup>19</sup> See footnote 46 below.

if these facts did not generally characterize Medicare and payor expectations and understandings under Part B reimbursement, it would have been economically irrational for Medicare and TPPs to continue to reimburse under that AWP-based system.<sup>20</sup> The accumulating evidence on the payment distortions associated with continuing to use the AWP as a relative value scale were finally formally recognized with 2003 *MPDIMA*.

20. It is alleged that the Defendant drug manufacturers understood these three facts and the resulting observation better than CMS, Medicare and payors; they knowingly exploited them by artificially inflating the list price of the relevant drugs (their AWPs and by implication any list prices formulaically linked to AWP) above the actual acquisition cost (AAC = ASP) of the providers, thereby increasing the “spread” (or “Return to Practice,” as the spread was called in the Lupron litigation<sup>21</sup>) earned by the provider of the drug and measured as the difference between provider reimbursement and drug acquisition cost. This increased spread affirmatively incentivized the relevant providers to prescribe the drug in question relative to alternative therapies, everything else equal, a belief confirmed by manufacturers’ strategic materials discussing spread for the drugs at issue here (see Section III.D below).

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<sup>20</sup> For example, if reimbursement were not cost-based in a relative value scale, incentives for inappropriate drug dispensing would be created, contrary to Medicare’s self interest. For research showing the effects of relative differences in drug profitability upon therapeutic choices, see Mireille Jacobson, A. James O’Malley, Craig C. Earle, Juliana Pakes, Peter Gaccione, and Joseph P. Newhouse, “Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?” *Health Affairs*, Mar/Apr 2006, Vol 25, No. 2, pp. 437-443. For a discussion of the effects of relative prices of services more generally, see Paul B. Ginsburg and Joy M. Grossman, “When the Price Isn’t Right: How Inadvertent Payment Incentives Drive Medical Care,” *Health Affairs*, Jul-Dec 2005, Vol. 24, pp. 376-384..

<sup>21</sup> Fraudulent manipulation of the “spread” in precisely this fashion was the primary allegation in the U.S. Government’s litigation against the manufacturer (TAP Pharmaceutical Products, Inc., or TAP) of the physician-administered drug Lupron. TAP pled guilty to fraudulent manipulation of the spread between AWP and the actual acquisition cost (AAC) of Lupron and paid in settlement damages \$875,000,000 plus interest; see *Lupron Sentencing Memorandum*. The “spread” is referred to as the “Return to Practice” by TAP, and the Government made use of this term throughout the *Lupron Sentencing Memorandum*.

21. These allegations suppose that those entities being incentivized could and would move market share. Considerable discovery materials, industry literature and academic research support these allegations.<sup>22</sup> This Court has explicitly recognized this alleged behavior, stating<sup>23</sup>

“Because doctors are involved as both retailers and as prescribing physicians, manufacturers, realizing the purchasing power of physicians, provide them with rebates, leading to large profits for the doctors on the prescription and administration of certain drugs. These profits now allegedly comprise a large percentage of these doctors’ income; according to Hartman, two thirds of the income of practice-based oncologists comes from the mark-up on injectable drugs. … Some experts have commented that ‘the financial incentives created by this profitability played a large and problematic role in prescribing decisions’ from 1998-2003 because ‘prescribers responded to these high margins by tending towards administering more (and more expensive) drugs than might be medically necessary or optimal for the health of the patient.’ …

In summary, when medical benefit expenditure data are poorly monitored and ‘tracking patient data is nearly impossible’, and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit (Berndt ¶ 191).”

22. I discuss below (Section III.D) the extent to which Defendants believed and relied upon the AWP scheme to incentivize physicians to move market share and thereby benefit from the alleged scheme. I note that the spread could be manipulated by either artificially inflating the AWP (to which reimbursement was formally linked under Part B) everything else equal; by reducing ASP, everything else equal; or by doing both. Of course, from the Defendants’ perspective, the most profitable strategy to increase spread would be to artificially inflate the AWP, holding ASP constant. In that case, the manufacturer would not decrease the revenue per unit sold while still increasing the incentives to move market share. These alternative methods

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<sup>22</sup> See footnote 20 for two recent academic articles further supporting this finding.

<sup>23</sup> *Memorandum and Order*, pp. 30-31.

of increasing the spread were recognized in the 2003 Report to the Congress from the Medicare Payment Advisory Commission (MedPAC) as follows:<sup>24</sup>

“In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, **manufacturers compete to increase their market share. This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers.** Although the manufacturer’s profit per dose will not increase with the rise in the listed price, the bigger difference between providers’ acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer’s product over its competitor. At the same time, coinsurance payments charged to beneficiaries will rise as the AWP increases. A hearing before the House Energy and Commerce Subcommittee on Health highlighted this outcome on September 21, 2001. One chemotherapy drug, Vincasar, which had an AWP of \$740, was sold to physicians for \$7.50 per dose. The beneficiary’s copayment (about \$150) was about 20 times providers’ acquisition cost. **Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy. They leave the AWPs at existing levels, and offer larger discounts directly to physicians who choose their drugs** over products offered by competitors. In this case, the manufacturers’ profit per unit dose will be less, but overall profits increase if the discounts result in increased market share. On May 5, 2003, the Office of Inspector General (2003) issued voluntary compliance guidelines for pharmaceutical manufacturers.<sup>25</sup> If a manufacturer manipulates the AWP to increase federal payments to its customers, the federal antikickback statute is implicated. In other words, it is illegal for a manufacturer knowingly to establish or maintain an AWP if one purpose is to manipulate the spread to induce customers to purchase its products (emphasis added).”

23. To date, the most publicized example of fraudulent AWP price inflation has been litigation against TAP Pharmaceuticals for their drug Lupron, which is not a Track 1 drug. The methods by which the “spread” or “Return to Practice” (RTP) was fraudulently manipulated and increased by the manufacturer of Lupron (TAP) and how that spread incentivized providers such

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<sup>24</sup> Medicare Payment Advisory Commission (MedPAC), Report to the Congress, *Variation and Innovation in Medicare*, June 2003 (*MedPAC Report*), pp. 156-157.

<sup>25</sup> That is, the *OIG Compliance Program Guidance*.

as urologists and oncologists to prescribe Lupron over alternative therapies have been well documented and admitted by Defendants in that matter and are helpful in understanding what occurred here as well. AWP was increased well above the estimated acquisition cost (EAC) or the average sales price (ASP) to the providers. Provider reimbursement rates were linked to AWP; ASP was decreased by substantial discounts, rebates, off-invoice payments and some admittedly illegal practices; TAP instructed the physicians dispensing Lupron and earning the inflated Return to Practice not to mention the aggressive price discounting to other doctors, to HCFA or to other payors (as discussed more fully in Section III.B below).<sup>26</sup> The resulting spread did incentivize the appropriate economic entities (physicians) to increase sales of Lupron relative to alternative therapies; market sales and market share were increased thereby. Indeed, some oncologists were named Defendants who earned millions of dollars in incentive payments from the “spread” or “Return to Practice.”

24. Lupron’s therapeutic competitor is the Track 1 drug, Zoladex, produced by AstraZeneca (AZ). As discussed below, to compete with Lupron, AZ adopted the same “Return to Practice” strategy, a practice which the independent expert to the Court, Dr. Berndt, has characterized (at his p. 46) as specific “egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians.” AZ also entered into a settlement agreement with the federal government for such fraudulent marketing practices.<sup>27</sup>

The 2003 *MedPAC Report* summarizes the spread competition between Lupron and Zoladex as follows:

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<sup>26</sup> All of these allegations are discussed in the *Lupron Sentencing Memorandum*.

<sup>27</sup> *Memorandum of Plea Agreement, United States of America v. AstraZeneca Pharmaceuticals LP*, In the United States District Court for the District of Delaware, Criminal Action No. 03-55-JJF, June 20, 2003 (Plaintiffs’ Exhibit 1).

"In October 2001, TAP Pharmaceutical Products, Inc. pleaded guilty to conspiring to violate the Prescription Drug Marketing Act. The central issue in the case was the allegation that TAP had encouraged urologists to bill Medicare for free samples provided by the company. TAP markets Lupron ..., a treatment for prostate cancer. Lupron competes with another drug called Zoladex .... In 2001, expenditures for Lupron and Zoladex were, respectively, the second and fourth highest of all drugs covered under Part B. Payments based on the easily manipulated average wholesale price (AWP) have allowed marketing abuses by manufacturers of these drugs. In the civil suit, the government alleged that the company had set AWPs far above the price that any of its customers paid and encouraged physicians to take advantage of the difference by billing Medicare for the AWP minus 5 percent. As part of its settlement with the federal government, TAP agreed to pay \$875 million dollars to resolve criminal and civil liabilities in connection with its pricing and marketing of Lupron. More than a dozen former TAP employees are still under indictment for using kickbacks and bribes to get doctors to use Lupron rather than Zoladex. This litigation also has led to further lawsuits by the Attorneys General in many states. These as yet unresolved suits focus on the discrepancy between AWPs and the actual acquisition prices available to retailers. Similar charges have been filed against the makers of Zoladex. One physician pleaded guilty to billing Medicare for between \$30,000 and \$70,000 for free samples he received from the manufacturer (Bureau of National Affairs 2002)." <sup>28</sup>

25. The methods by which any other physician-related treatments (*e.g.*, other treatments for cancer; HIV/AIDS treatments; treatments for renal disease and hemophilia; treatments for transplant recipients; some nausea drugs; the use of nebulizers; and other therapies) would be incentivized are the same.

#### **B. Spread Competition in This Matter Differs From Standard Price Competition and Does Not Benefit Consumers or Payors**

26. Spread competition generally was strategically implemented by manufacturers once a drug manufacturer was confronted with competition from a new therapeutic or generic competitor. This type of competition must not be confused with normal price competition. While the spread competition in this matter may have involved competitive price reductions, it

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<sup>28</sup> *MedPAC Report, op. cit.*, p. 158.

did not result in pro-competitive price reductions to consumers, as is usually the case when price competition occurs. As a matter of economics, in a competitive market, consumer welfare is increased when costs are reduced; prices reflect those cost reductions and consumers switch to those products with lower prices/costs. In this industry, manufacturers' ASPs and actual acquisition costs to providers and market intermediaries **were reduced**, but consumers/payors were either steered or switched to those products that were priced higher (i.e., required higher reimbursement rates), or they paid a higher price related to an inflated AWP, or they continued to pay for drugs at the same prices that did not reflect cost reductions. Such a market result is diametrically opposite to a normally competitive market result. Yes, spread competition occurred in response to competitive entry; however, as in the Lupron matter, it was the manner by which the competition was implemented that constituted fraudulent marketing practices. The spread competition exploited by the Track 1 drug manufacturers in this case is not normal pro-consumer competition. An attempt to characterize it as such would be misleading.

27. While standard price competition does not require that consumers know, or have expectations about, the costs of the competing suppliers in a market, successful price competition does require signaling consumers about the lower prices offered by the competitors seeking to gain market share. The spread competition alleged in this matter was successful precisely because competing suppliers actively and secretly suppressed information **from end payors** about the lower prices offered providers. Those lower prices were offered to middlepersons (through discounts, price offsets and/or free samples to be sold illegally) not to consumers or end payors. Selected examples include the following:

a) The *Lupron Sentencing Memorandum* (at pages 25-26) describes “the training program … by top Sales management at TAP … regarding pricing strategy” as follows:

- “One of the slides, regarding pricing strategy, contains the following:

‘What should I say to my physicians about contract confidentiality? Explain to physicians that discussing price could potentially put reimbursement in jeopardy.

Doctor by discussing your costs of Lupron with other physicians, you run the risk of that information getting back to HCFA. If HCF [sic] then realized that AWP is not a true reflection of the price, the AWP could be affected, thus lowering the amount you may charge.’

- On the PowerPoint slide for the instructor, the following text appears:

‘The main point to make to physicians is that confidentiality clause is a protection for them. If word is leaked back to HCF[sic]/Medicare that the cost of Lupron is going down, they very well may take steps in reducing allowable. This tactic should help prevent physicians talking amongst themselves.’

- TAP’s entire program of discounts – designed initially to replace the free product discount program – was premised upon the notion that doctors would not pass along any discounts they received in purchasing to patients and their insurers, including Medicare. The Government has concluded that, just as TAP and its employees did not expect physicians to pass along to their customers any price discounts, TAP and its employees also did not expect doctors to pass along any free drug ‘discounts’ and fully expected and intended doctors to bill patients for free drugs.”

b) AZ likewise inserted provisions in its buying group contracts with physicians that the providers would have to maintain the confidentiality of the terms and conditions of

the contracts for a period of three years.<sup>29</sup> David R. Brennan, AZ's President, testified that this was AZ's policy.<sup>30</sup>

- "Q. Was there a procedure in place for AstraZeneca to publish the prices that were arrived at in urology group buy contracts to the marketplace?
- A. I'm not aware that that is something we would do, no.
- Q. In fact, it is something you didn't do, right?
- A. Yes.
- Q. They were actually confidentiality clauses in the urology group contracts, right?
- A. Sounds like it, yes."

He likewise testified that AZ made no effort to communicate the discounts it gave to providers to individuals who were administered Zoladex.

- "Q. But the payors did not know what you were selling Zoladex to doctors for, right? ...
- A. I mean, if there is confidentiality associated with it, then we certainly wouldn't be the ones to do it. But I think everybody was aware that there were discounts from AWP and from WAC.
- Q. Everyone was aware. The consumer getting a shot of Zoladex was aware of the discount? ...
- Q. Yes or no?
- A. I don't know the answer to that.
- Q. Do you think so? Do you think so? Do you think the consumer getting a shot of Zoladex in his abdomen knew that the percentage of the co-pay he had to pay was higher than it would have been had the reimbursement been based on the actual acquisition cost of the drug rather than AWP? DO you think the consumer knew that?
- A. I don't know. I honestly can't say I know. I mean, I think that there was incentive in the system. There was co-pays in the system. It is difficult to say, for me to say that I know exactly what somebody who was getting a shot would know.
- Q. Was there ever an effort made by AstraZeneca to let the consumer know exactly what it was that their doctor purchased the drug for?
- A. Not that I am aware of."<sup>31</sup>

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<sup>29</sup> See, e.g., May 1, 1996 Contract with Urology Network of Central Ohio, Plaintiffs' Exhibit 982U (AZ0069688-701).

<sup>30</sup> Deposition of David R. Brennan, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, February 14, 2006, pp. 29-30.

- c) BMS employed pricing contracts that required confidentiality concerning the price offsets inducing spread competition. For example, BMS's former Director of Marketing for Oncology, Christof Marré, testified that, in response to generic competition, BMS would offer pricing discounts contained in confidential contracts:<sup>32</sup>

“When almost any drug has exclusivity, you sell the drug at list price. But once you face generic competition, the generics try to gain market share by bringing the price down and offering discounts to their customers. So, as the branded company, your choice is either to quickly lose business if you don't bring your contract prices in line with the market, or to offer competitive prices and hope to maintain a significant volume share of the market.”<sup>33</sup>

However, in keeping with an “industry standard,” BMS would not lower the WLP (wholesale list price, or WAC).<sup>34</sup> BMS would employ this pricing strategy – resort to confidential contract discounting while maintaining a constant and high WLP (and therefore AWP) – when other BMS drugs, including Taxol, lost exclusivity. In response to generic competition, BMS lowered its contract prices paid by physicians without changing the WLP.<sup>35</sup> Marre confirmed that this pricing strategy “managed to slow down our volume erosion and at some point we even managed to increase our sales volume of Taxol through OTN, and we also increased our overall share of the Paclitaxel market.”<sup>36</sup>

<sup>31</sup> *Ibid.*, pp. 30-31.

<sup>32</sup> Deposition of Christof A. Marre, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action 01-CV-12257-PBS, August 26, 2005, p. 38 (“Q. And the contract – the prices contained in contracts between BMS and customers, those are confidential and not publicly available, correct? A. Yeah.”).

<sup>33</sup> *Ibid.*, p. 40.

<sup>34</sup> *Ibid.*, pp. 85-87.

<sup>35</sup> *Ibid.*, pp. 100-101.

<sup>36</sup> *Ibid.*, p. 107.

- d) Schering-Plough (S-P) required that the terms of their pricing contracts be kept confidential as indicated by a Warrick Pharmaceuticals contract confidentiality clause: “Customer shall maintain the confidentiality of all pricing, marketing or other Warrick product information, including this agreement it’s terms and conditions throughout the duration hereof and for a period of three (3) years following the effective date of expiration or termination.”<sup>37</sup>
- e) Johnson & Johnson (J&J) similarly recognized the need for hiding their pricing to different customer groups. In a memo regarding “general background on AWP and relative spread,” Mike Ziskind states:
- “When we discuss the cost of therapy and when the cost of Remicade is compared to other treatment options, it is important to understand the audience’s perspective. For example, if we were to routinely use cost to wholesalers we would set payers’ expectations too low. If we were to routinely use AWP, we might scare off some providers who are concerned about acquisition cost. My recommendation is to adopt some standard description so that the audience knows what “cost” is being cited. I would not, however, include both cost figures in the same presentation because that may highlight spread more than we would like, even though our spread is well in the range of other infused drugs.”<sup>38</sup>
- f) Even though GlaxoSmithKline (GSK) is no longer a Defendant in this matter, its strategic materials provide evidence of the Defendants’ conduct generally in cloaking the spread competition from market scrutiny.

“Contracting directly with the Oncology clinics could put Glaxo Wellcome in the Justice Department’s spotlight by lowering the

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<sup>37</sup> See Plaintiffs’ Exhibit 422 (WAR0043141-48 at WAR0043146).

<sup>38</sup> Memo from Mike Ziskind to Jason Rubin, Re: New Vial Sizes, July 6, 1999, Plaintiffs’ Exhibit 260 (MDL-CEN000085404-5). See also samples of Ortho Biotech Inc contracts. For example, Plaintiffs’ Exhibit 255 (MDL-OBI00054909-13 at MDL-OBI00054910, ¶7) and Plaintiffs’ Exhibit 256 (MDL-OBI00055078-82 at MDL-OBI00055079, ¶7)

acquisition price on Glaxo Wellcome products purchased by these clinics without lowering the NWP.”<sup>39</sup>

“I am recommending that we do NOT take a price increase of any kind in March and hold off until 4Q of this year to re-evaluate a potential price increase. Reasons are as follows:[...] 2. Due to greater government focus on injectable drug pricing in the oncology clinic setting, it is wise for SB to further space the timing between price increases on Kytril. If, for example, SB were to raise the price of Kytril in November of this year, a solid 18 months would have passed since the last price increase.”<sup>40</sup>

28. The markets and competition in the markets at issue in this litigation are not analogous to the markets and competition in the markets for such consumer products as eggs, soda pop or automobiles, as Defendants would like the Court to believe. The markets for the first two consumer products are sufficiently competitive that prices will be driven in equilibrium toward costs, whether or not consumers have expectations about or knowledge of those costs. Price information is aggressively and accurately disseminated through mailings, flyers and a variety of media sources explicitly informing consumers of price reductions aimed at capturing market share. That is the nature of price competition. The information available to a consumer purchasing a new automobile is also extensive. Resale market prices of similar makes and recent vintages are available through such information sources as the Blue Book, a variety of web-based price information sources, newspaper ads for used cars, and used car dealers. Consumers make such purchases infrequently and carefully, given that such a purchase is usually a relatively large expenditure to the consumer. They usually research alternative costs and shop dealers against one another.<sup>41</sup> In all three of these markets, buyers shop for themselves on the basis of

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<sup>39</sup> 1997 Oncology Clinic Contracting Strategy, at GSK-MDL-ZN02-072192.

<sup>40</sup> Letter from Pearl Pugh to Kevin Lokay, 1/27/00, GSKMDLKYTR02-0043706-7.

<sup>41</sup> Moreover, central features of the pharmaceutical market are ignored by these simple and incorrect analogies. Two of these missing features are the principal-agent problem and the presence of insurance, both of which I discussed in my Declarations in Support of Class Certification (9/3/04 and 12/16/04).

price. In one of the markets, resale markets exist. Since sellers compete on the basis of price, they must communicate price to consumers, and in that case the buyers do not need to know the seller's acquisition costs, only the price at which the seller offers the product. This is competitive market reasoning, and is correct in that context. Competition among sellers should drive prices down to long-run average costs.

29. This reasoning **is not correct** in bargaining models, which better describe the relationship between payors and physicians in the markets at issue here. The shopping that occurs among providers and payors involves RFPs (Request for Proposal) and negotiations subsequent to receipt of proposals. There is no resale market to provide price information, since resale of drugs is against the law.<sup>42</sup> The reimbursement rate formulae that are negotiated will be computerized into relevant reimbursement data bases and will be used to determine the reimbursement rates for a substantial number of claims (from thousands to millions) submitted by the provider over time for a variety of services, drugs and durable medical equipment.

It is well known that in a bargaining context, the information available to both parties affects the outcome of bargaining, including its efficiency properties.<sup>43</sup> When TPPs and providers negotiate, information (and in the absence of accurate information, **expectations about such information**) concerning the actual spreads between AWPs and provider acquisition costs determine the negotiating positions taken by both parties. These expectations inform beliefs about the "reservation drug price" or "reservation drug cost" to which TPPs can push providers during the negotiation. When information is asymmetrical, the party with less information and

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<sup>42</sup> The Prescription Drug Marketing Act of 1987 as modified by the Prescription Drug Amendments of 1992 (P. L. 102-353, 106 Stat. 941) on August 26, 1992 forbids such resale.

<sup>43</sup> See Jean Tirole, *The Theory of Industrial Organization*, MIT Press, 1989, pp 22-25.

incorrect expectations is unable to strike a “good bargain” or “good negotiation” regarding reimbursement for physician-administered drugs.

That is certainly the case in this litigation: the providers have known the acquisition costs of their drugs; the providers have understood and acted upon the manufacturers’ directions to keep secret all information about discounts, free samples and price offsets which determine provider acquisition costs; consequently, payors including Medicare have had incomplete information to effectively negotiate physician-administered drug reimbursement rates reflecting acquisition costs. Indeed, the evidence indicates that even those payors who have purchased physician-administered drugs directly<sup>44</sup> have not made effective use of that information (for reasons discussed below in Section VI and Attachment E). In this situation, the negotiating effectiveness of all payors Class-wide has been constrained by expectations regarding spreads that were incorrect and actively kept incorrect by the manufacturer and provider scheme not to divulge acquisition cost information.<sup>45</sup>

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<sup>44</sup> For example, TPPs with staff-model HMO subsidiaries which purchase physician-administered drugs directly.

<sup>45</sup> An economic literature characterizes market equilibria in such bargaining situations. Specifically, in a Nash or Roth-Nash model of bargaining, the “reservation utility” (in this case, the utility that the provider could achieve if no reimbursement agreement was reached) is relevant to determining the outcome of a bargain for the TPP. If a TPP bargaining with a physician believed the physician were forgoing profits of X (based upon expectations about the reservation acquisition cost) by not striking a deal, the outcome would be different than if the TPP thought the physician were forgoing profits of 100X. What a TPP believes (expects) about the ASP is relevant to the economic outcome of the bargaining between the TPP and physician.

Deposition testimony confirms this. See Deposition of Joe Spahn, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, November 30, 2004, pp. 53-55:

- “Q. Okay. So we can agree that Anthem understands that the amounts that it’s reimbursing providers in relation to drugs they administer in office is something greater than what they pay to acquire those drugs? ...
- A. The only issue I have with that is I don’t know what they actually pay for the drug. So it’s difficult to answer. But I would assume that we’re paying an adequate rate because they stay in the network to not cancel their contract. ...
- A. By ‘an adequate rate,’ I mean it’s a rate that causes them to continue to participate with Anthem as a contracted provider. ...

### C. Spread Competition was Practiced by Manufacturers of Single-Source and Multi-Source Drugs

30. Reimbursement for the Track 1 single-source drugs under Part B is subject to a single or sometimes limited number of J-codes (or other HCPCS codes), and has been based, until 2005, upon the lesser of some percentage of AWP and some measure of provider acquisition cost.<sup>46</sup> As a result, the AWPs and the ASPs for all NDCs of these drugs were

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- A. We want to pay a rate that is – that is fair, reasonable and equitable to the provider, while at the same time controlling cost of care. ...
  - A. And maintaining an adequate network, ..."'

Mr. Spahn's belief that his TPP pays a "rate that is ... fair, reasonable and equitable to the provider, while at the same time controlling cost of care" reflects the understanding I find generally among TPPs in Class 3. Specifically, "every commercial transaction involves an element of trust," as noted by Daniel McFadden while quoting another Nobel Laureate, Kenneth Arrow. I discuss this "element of trust," its implications for Class 3 causation and damages, and the source of the quote in ¶¶ 98 & 99 below.

<sup>46</sup> It is useful to provide a brief summary of statutory provisions determining Medicare reimbursement for Part B drugs by time period.

#### Prior to 1992:

"Before 1992, Medicare carriers generally paid for drugs based on physicians' estimated costs as measured by the AWP." (Source: Medpac, "Report to Congress: Variation and Innovation in Medicare," Chapter 9, "Medicare payments for outpatient drugs under Part B," June 2003, pp. 152).

#### 1992 through 1997:

"Payment for a drug ... is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. ... For multiple-source drugs, payment is based on the lower of the estimated acquisition cost ... or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." (Source: 42 CFR 405.517, Revised October 1, 1996).

#### From 1998 – 2003:

"Payment for a drug or biological ... is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological. ... For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. (Source: 42 CFR 405.517, Revised October 1, 2003).

#### For 2004:

"The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA) provides that as of January 1, 2004, the payment limits for drugs and biologicals are based on 85 percent of the April 1, 2003 Average Wholesale Price (AWP), for those drugs and biologicals furnished on and after January 1, 2004. ... The Medicare payment limits [%\*AWP] for drugs and biologicals not paid on a cost or prospective payment basis, and furnished on or after January 1, 2004, through December 31, 2004, are as described" for a variety of specific Part B medications, including blood clotting factors; new drugs or biologicals (as approved by the FDA

vulnerable to strategic manipulation by the manufacturer of that drug. The manufacturer of the drug could inflate the AWPs; reduce the ASPs; or do both, as discussed by the *MedPAC Report* as cited in my ¶ 22 above.

31. For multi-source (for the most part generic) physician-administered drugs reimbursed under Medicare Part B, reimbursement is generally based upon the lesser of some measure of provider acquisition cost and some percentage of the median of the AWPs of all generic sources of the drug.<sup>47</sup> Obviously, any manufacturer of a physician-administered multi-source drug can compete on spread by simply reducing its drug's ASP relative to the median AWP. In that case, the AWP inflation reflects the fact that reimbursement linked to the median AWP will invariably be inflated, usually substantially, relative to the provider acquisition cost. The question remains, can a multi-source manufacturer also inflate the AWP upon which reimbursement is based, everything else constant?

subsequent to April 1, 2003); pneumococcal and hepatitis B drugs and biologicals; certain drugs studied by the OIG and GAO; infusion drugs furnished through an item of implanted durable medical equipment; drugs and biologicals not described above. The percentage off AWP for these different medications varies from 80-95%, some based on the April 1, 2003 AWP.

From § 20.2: "For a single source drug or biological, the AWP equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of: the median AWP of all generic forms of the drug or biological; or the lowest brand name product AWP. (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003).

**From January 1, 2005:**

"Per MMA of 2003, beginning 1/1/05, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on 106% of the Average Sales Price (ASP). CMS will supply contractors with an ASP drug pricing file for payment of drugs. This pricing file shall be provided to contractors by CMS quarterly. Contractors will continue to price covered drugs not on the file." (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004).

<sup>47</sup> As discussed in the preceding footnote, reimbursement for multi-source physician-administered drugs was to be at the lesser of some percentage of the median of the AWPs of all generic sources of the drug and the lowest AWP of all branded sources. For most cases, the median of the generic AWPs was less than the lowest branded AWP.

32. Although the median itself is not readily subject to strategic manipulation by *any single generic manufacturer*, the distribution of AWPs for generic sources of the drug is subject to the strategic manipulation of all generic manufacturers, and, thereby the median AWP. Even if no individual multi-source drug manufacturer has an incentive to independently “inflate” its own AWP,

- a) It is true that **all** manufacturers of a multi-source drug have the incentive to maintain the median AWP as high as possible, to increase the spreads of all these manufacturers relative to potential **alternative therapeutic competitors**.
- b) It is generally true that generics launch with an AWP fairly close to the AWP of the related branded drug (by NDC). In many cases, the generic AWP is some 5-15% below the branded AWP; in some cases, a generic AWP may be greater than the branded AWP. The precise setting of the AWP may be determined by the timing of the generic entry.
- c) It is generally true that once the generic manufacturers set their AWPs, most manufacturers maintain them at constant levels.<sup>48</sup>
- d) The result seems to be a tacit informal Nash equilibrium<sup>49</sup> in the dispersion of generic AWPs, which are fairly similarly discounted off the branded AWP for which

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<sup>48</sup> For example, Schering-Plough/Warrick confirms this in their Concise Statement of Undisputed Material Facts in Support of Schering-Plough Corporation’s and Warrick Pharmaceuticals Corporation’s Motion for Summary Judgment, March 15, 2006. At ¶ 36, they state “Warrick suggests an AWP at launch and has, in almost all instances, not changed the AWP for the life of the product Weintraub. Decl. ¶¶ 11, 13; Addanki Decl. ¶44.” At ¶ 42, they state “Since 1995, Warrick’s AWPs for 0.083% and 0.5% solutions of albuterol have stayed the same. Addanki Decl. ¶44, Exs. 4A-B.” See also Marre Deposition: “I believe it’s an industry standard that once a drug was generic, the lists price stays wherever it was when it went generic and is not updated” (p. 86).

<sup>49</sup> For example, see Dennis Carlton and Jeffrey Perloff, *Modern Industrial Organization*, Third Edition, 2000: “A set of strategies is called a **Nash equilibrium** if, holding the strategies of all other firms constant, no firm can obtain a higher payoff (profit) by choosing a different strategy. Thus, in a Nash equilibrium, no firm *wants* to change its strategy.” (p. 157, **emphasis in original**)

the generics are equivalent, a Nash equilibrium not unlike that noted by Dr. Berndt with regard to the observed similar relationship between AWP and WAC for most branded drugs.<sup>50</sup>

- e) Once the dispersion is set, the generic manufacturers compete amongst themselves on spread through the reduction of their ASPs. The resulting price reductions (in ASPs) do not reach the payors, as in standard competitive markets; instead, they induce middlepersons to move market share.

The apparent Nash equilibrium in the dispersion of generic AWPs is often linked to the AWP of the branded drug for which the generics are bioequivalent. Hence, the entire dispersion, including the median, is artificially inflated to the extent that the branded AWP is artificially inflated. This observation is certainly relevant to the dispersion and median of the AWPs for albuterol, since they have been set relative to Proventil's AWP. To the extent that the median is thereby inflated, the spreads of generic albuterol will be further inflated relative to any ASP.

33. I document such clusters of generic AWPs for selected multi-source drugs in Figures 1 and 2. I find the following.

- a) In Figures 1.A-1.C, I present clusters of Albuterol AWPs over time and in comparison with the AWPs of Proventil and Ventolin.<sup>51</sup> Note the following:

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<sup>50</sup> In commenting on the consistent relationship between the list prices AWP and WAC, Dr. Berndt in his Report of February 2005 states (at p. 10), "In summary, for brand name/single source self-administered drugs, while the underlying rationale supporting a 20-25% spread between AWP and WAC has long disappeared, manufacturers and retailers appear to be locked in to this practice. In the jargon of economics and game theory, what we observe is a Nash equilibrium in which for all players AWP exceeds ASP and WAC. There is no incentive for any brand name manufacturer of self-administered single-source drugs to align its AWP to a level much closer to WAC."

In this case, we observe for generic drugs a dispersion of AWPs related to the AWP of the brand name drug for which the generic drugs are equivalent. No single generic can realistically independently influence the median AWP. However, the greater the median, the greater will be the spread between the ASPs and the median AWP; the more competitive will be **all generics** in that group **relative to the generics of therapeutic substitutes**, everything else equal. Competition among generics within that group will be driven by the spread created by ASP competition.

- Figure 1.A presents a scatter-plot series of the AWPs for all generic NDCs for albuterol sulfate over time for J-Code J7611. It would appear that several prices deviate considerably from the remaining clusters in each bar graph. However, the three highest AWPs for each year belong to a repackager who sells its product in an atypical unit dose which according to CMS regulations is not to be included in the calculation of the median.<sup>52</sup>
- Excluding the NDCs for this repackager, the cluster of generic AWPs reduces to that presented in Figure 1.B. Furthermore, my analysis indicates that the Schering-Plough/Warrick AWP is the median in many of these years.
- Finally, Figure 1.C demonstrates how the generic AWPs are set relative to the branded AWPs for this J-Code.

- b) In Figure 2, I present clusters of the AWPs of Taxol and generic paclitaxol over time in a context similar to that of Figure 1.C.<sup>53</sup>

I conclude that generic manufacturers do cluster their AWPs for certain physician-administered drugs, suggesting that both the AWP and the ASP may enter into the inflated spread generated by the AWP Inflation Scheme.

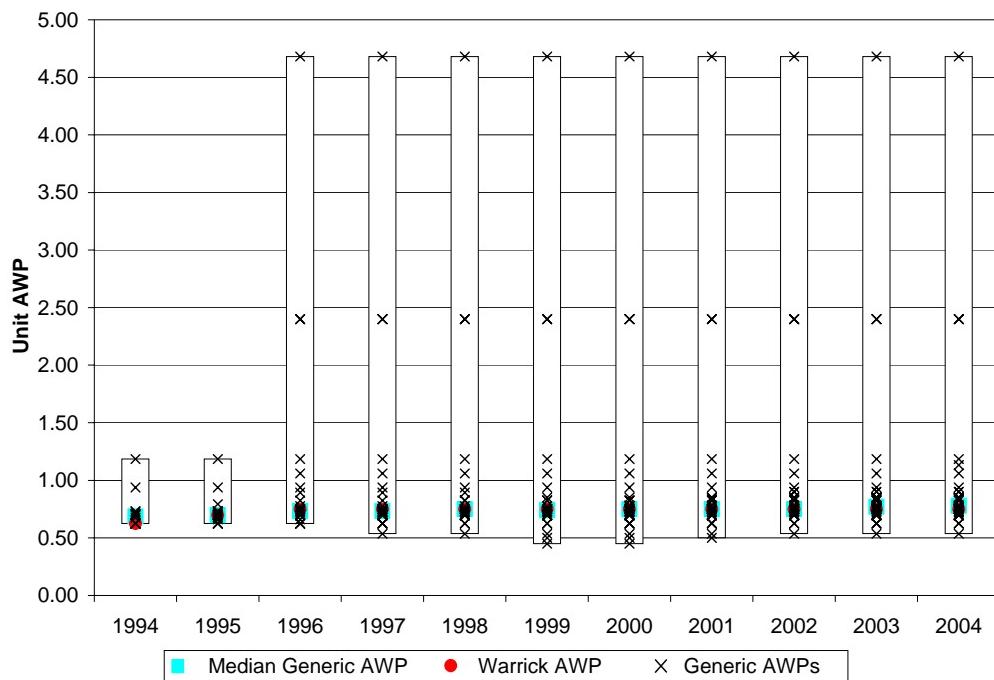
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<sup>51</sup> Figures 1.A-1.C present AWP pricing data for the manufacturers of Proventil and Ventolin and the generic manufacturers of albuterol sulfate 0.5% (J7611) from 1991-2004. AWPs are expressed as prices per extended unit. The median generic AWP has been calculated as the median of all generic forms of albuterol sulfate 0.5%.

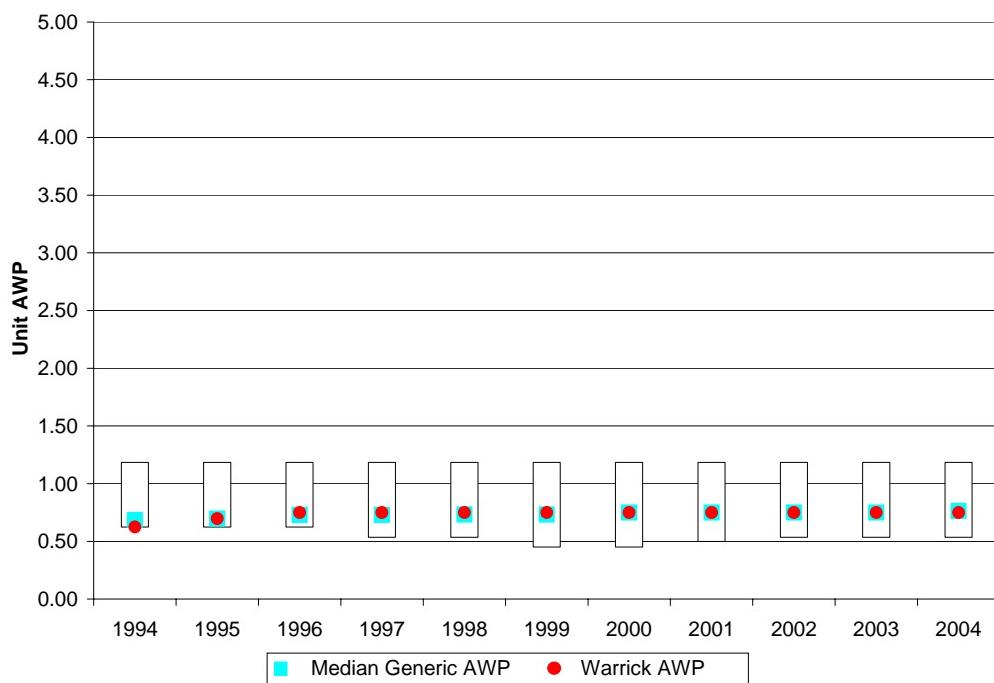
<sup>52</sup> See sections 20.4 and 20.5.5, Calculation of the AWP in the CMS Manual System, Pub. 100-04 Medicare Claims Processing Department of Health & Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), Transmittal 397, December 16, 2004, Change Request 3232: "In applying this procedure [calculation of median], carriers use the package sizes that are most commonly used for the most frequently administered dosage of the drug."

<sup>53</sup> Figure 2 presents AWP pricing data for the manufacturers of Taxol and Onxol and the generic manufacturers of paclitaxel (J9265) from 1991-2004. AWPs are expressed in terms of the fundamental billing unit. The median generic AWP has been calculated as the median of all generic forms of paclitaxel.

**Figure 1.A**

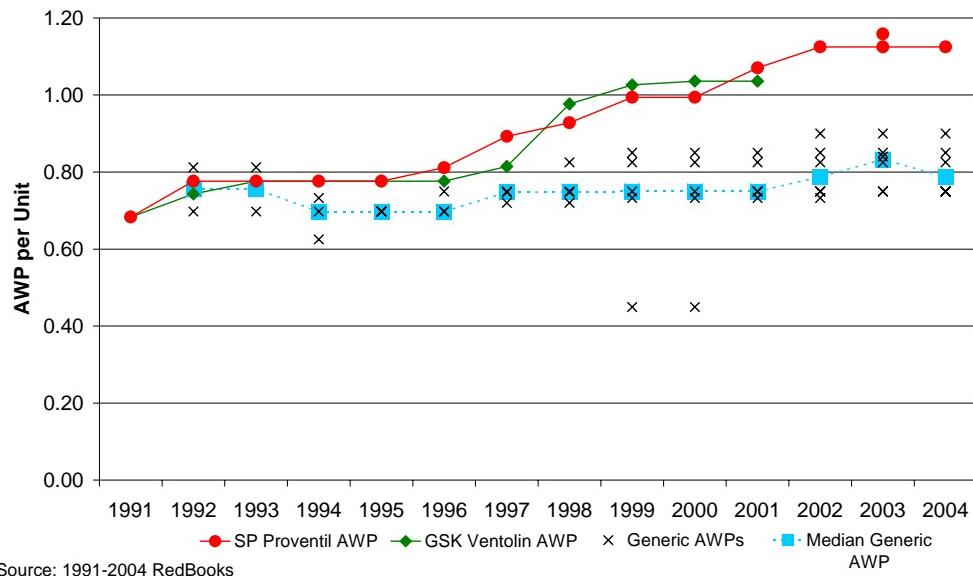


**Figure 1.B**



**Figure 1.C**

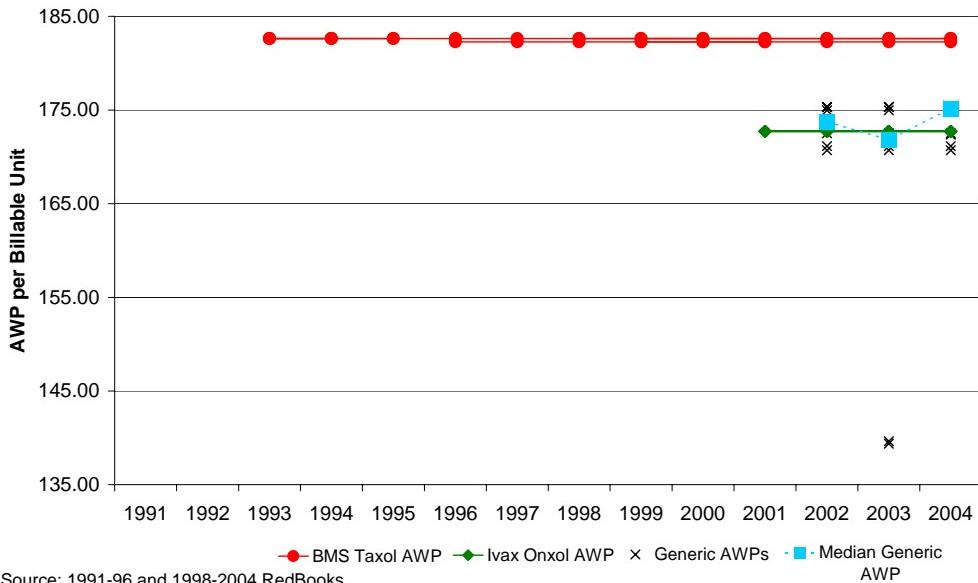
**Proventil, Ventolin, and Albuterol Sulfate 0.5% (J7611)  
AWP per Unit**



Source: 1991-2004 RedBooks

**Figure 2**

**Taxol, Onxol, and Paclitaxel (J9265)  
AWP per Billable Unit**



Source: 1991-96 and 1998-2004 RedBooks

**D. Examples of the Effects of the AWP Inflation Scheme on the Spreads of Track 1 Defendants' Drugs**

34. In this Section, I present price data summarizing the economically motivated pricing strategies of Defendants to manipulate the AWP to incentivize providers to move market share, resulting in extraordinary spreads that were certainly not expected or understood by payors and caused overcharge injury to members of Class 2 and Class 3. I proceed selectively by manufacturer and drug, gathering published AWPs over time for drugs at issue in this trial. For exposition only, I include data for a Track 1 Defendant, GSK, which settled out of the litigation. Using the data provided by the manufacturers, I have calculated the ASPs by NDC for each drug. The difference between AWP and ASP is referred to as the spread.

35. For diagnostic purposes in the remainder of this section, I use the measure of spread calculated simply as  $(AWP - ASP)/ASP$  to provide an index of the injury and damages resulting from the AWP Inflation Scheme. Using this measure for selected Track 1 drugs by manufacturer, I demonstrate the size of the spreads and how the spreads were strategically exploited to compete against new therapeutic and/or generic competitors. While presenting these measures of spreads and the underlying competition, it is useful to keep in mind the preceding discussion that the competition being described is not pro-competitive in the usual sense of the concept, *i.e.*, where price competition reduces consumers prices. In all of these cases, the spread competition was induced by normal competitive impulses for manufacturers to lower prices to gain market share but resulted in increased profits to providers and increased costs to consumers.

## 1. Overview

36. Table 1 presents the calculated spreads for particular Track 1 drugs for particular years. For the most part, the spreads for Track 1 manufacturer drugs in Table 1 were large in the earlier part of the Class Period and increased, in some cases considerably, over time, in response no doubt to increasing therapeutic and/or generic competition.

37. For some perspective, I have included the spreads for several of the important (by sales volume) NDCs for Lupron in Table 1, which were, of course, subject to the *Lupron Sentencing Memorandum* and TAP's guilty plea. During the Class Period, the courts found that TAP promoted Lupron through illegal sales of free samples, questionable payments, price offsets and other practices all of which were reflected in spread manipulation.<sup>54</sup> TAP pled guilty to the allegations and was fined substantially by the federal government. I performed the analyses in support of class certification and the calculation of damages in the private MDL Lupron litigation. In that analysis, I found that TAP varied the spreads of Lupron NDCs *annually*, *indeed sometimes quarterly*, to strategically move market share among its alternative NDCs. One strategic desire revealed by TAP was to move the market from its shorter-length presentations to its longer, more costly (three-month and four-month) presentations. To do so, TAP increased the spreads of the presentations for which it sought to increase market share while reducing the spreads for presentations which were no longer being actively promoted.

For example, TAP increased the spread of NDC 00300-3336-01 from 70.2% in 1996 to 292.1% in 1998 (in Table 1). Between 1997 and 2000, TAP reduced the spread of NDC 00300-2440-01 from 143.1% to 35.7%. By 1998, TAP had increased the spread of NDC 00300-3683-

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<sup>54</sup> See *Lupron Sentencing Memorandum, op. cit.*

01 to 301.6%. It reduced this spread to 188.1% by 2000, which was still substantial. In all cases, the federal government found these spreads excessive and the marketing practices creating them illegal.

38. In the remainder of this section, I selectively describe patterns of spread competition as increased spreads were implemented strategically by the Track 1 manufacturers to move market share. I note that the spreads for many of these drugs are greater than the spreads revealed with many Lupron NDCs.

**Table 1: Illustrative Spreads**

Defendant	Drug Name <sup>55</sup>	Spread (Year)	Spread (Year)
AstraZeneca	Zoladex	46.7% (1995)	149.7% (2001)
Bristol-Myers Squibb	Blenoxane	72.8% (1998)	85.9% (2002)
Bristol-Myers Squibb	Taxol	27.0% (1997)	128.7% (2002)
Bristol-Myers Squibb	Cytoxan	257.7% (1997)	676.8% (1999)
Bristol-Myers Squibb	Rubex	180.7% (1995)	66.2% (2001)
Bristol-Myers Squibb	Vepesid	70.7% (1995)	1131.7% (1999)
Johnson & Johnson	Remicade	32.1% (1999)	31.9% (2001)
Schering-Plough	Proventil	53.8% (1993)	38.9% (2001)
Warrick (Schering)	Albuterol Sulfate	186.9% (1995)	651.4% (2002)
TAP	Lupron 3-month	70.2% (1996)	292.1% (1998)
TAP	Lupron Depot-Ped	143.1% (1997)	35.7% (2000)
TAP	Lupron 4-month	301.6% (1998)	188.1% (2000)

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<sup>55</sup> The spreads for the following drugs have been reported for a specific NDC identified as follows: Zoladex (00310-0960-36); Blenoxane (00015-3010-20); Taxol (00015-3476-30); Cytoxan (00015-0548-41); Rubex (00015-3352-22); Vepesid (00015-3061-20); Remicade (57894-0030-01); Proventil (00085-0209-01); Albuterol (59930-1500-08); Kytril (00029-4149-01); Zofran (00173-0442-00); Lupron (00300-3336-01, 00300-2440-01, 00300-3683-01).

## 2. AstraZeneca – Zoladex

39. One example, already identified as “egregious” by Dr. Berndt and discussed explicitly by the *MedPAC Report* (see ¶¶ 23-24 above), is the AstraZeneca (AZ) drug, Zoladex. As noted earlier, Zoladex is a treatment for prostate cancer. Zoladex is a LHRH (luteinizing hormone-releasing hormone) that is therapeutically similar to TAP’s Lupron, which was already on the market when AZ launched Zoladex.<sup>56</sup> Both launched prior to 1991, the beginning of the Class Period.

40. In order to compete with Lupron, AZ exploited the same tactics used by TAP for marketing and promoting Zoladex. Indeed, AZ was investigated, sued and forced to enter into a settlement plea agreement, also subject to damages paid to the federal government.<sup>57</sup> The spreads for two years presented in Table 1 are 40.7% (1995) and 149.7% (2001). In Figure 3, I

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<sup>56</sup> Lupron launched in June 1985 and Zoladex launched in January, 1990.

<sup>57</sup> See Plaintiffs’ Exhibit 3, the Transcript of Hearing, June 20, 2003, United States of America, Plaintiff v. AstraZeneca Pharmaceuticals LP, Defendant, in which AZ pled guilty to one count charging it with violation of the Prescription Drug Marketing Act, 21 U.S.C. §§ 353(c), 331(t) and 333(b)(a)(B), by causing the sale of drug samples.

As admitted by AZ’s counsel therein (p. 8):

“...Beginning in or about 1993, and continuing at least until July 1996, some Zeneca employees provided free samples of Zoladex to physicians, knowing and expecting that certain of those physicians would prescribe and administer samples to their patients and thereafter seek and receive reimbursement, in violation of the Pharmaceutical Drug Marketing Act.

When this was done, one of the objectives was to induce the physician to order Zoladex. It was an objective of the physicians to bill for the free samples in order to increase their income....”

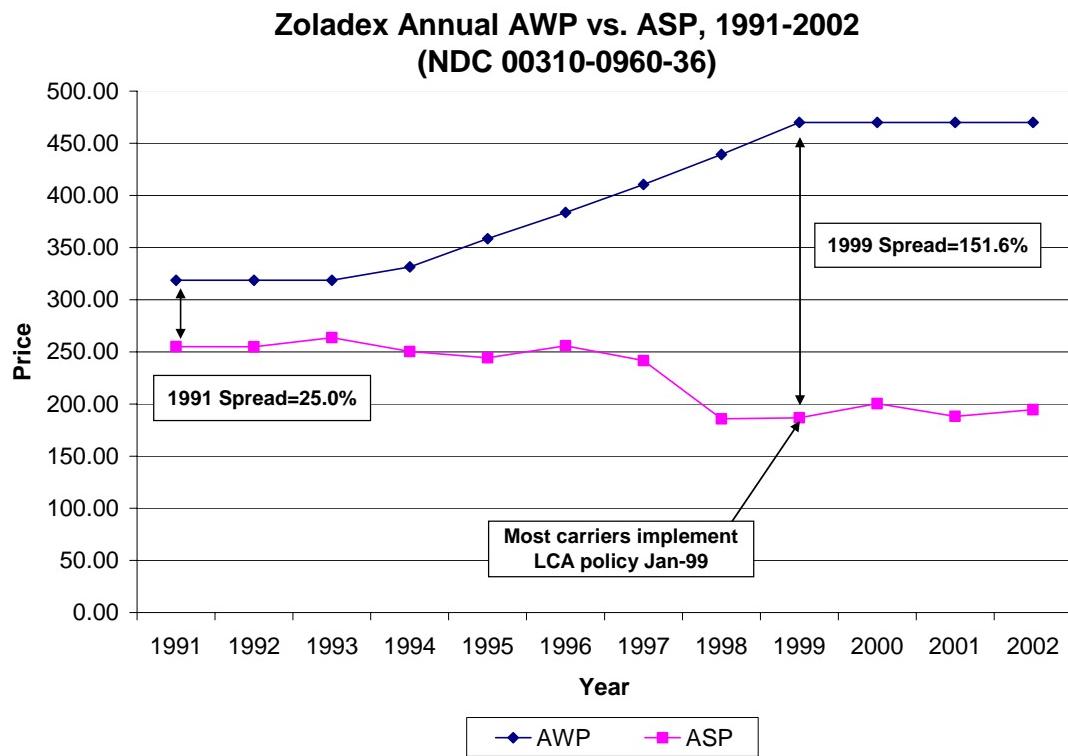
Government counsel summarized the case as follows (p. 9):

“...Beginning in or about 1993 and continuing to at least July 1996, the defendant, which is called Zeneca here, through its employees, provided thousands of free samples of Zoladex to physicians knowing and expecting that certain of those physicians would prescribe and administer those drug samples to their patients and thereafter seek and receive reimbursement for the free samples....”

See also Plaintiffs’ Exhibit 1 (*Memorandum of Plea Agreement*) and related litigation, *United States of America v. Robert Berkman*, Criminal Action No. 03-45-JFF (Plaintiffs’ Exhibit 5).

have charted the spreads annually for the same NDC (00310-0960-36), using the Average Sales Prices (ASP) and AWPs.

**Figure 3:**



41. Figure 3 demonstrates several important points. From 1991 through 1994, the spread between ASP and AWP remained steady, at or below 25%. Spread inflation was not pursued. However, beginning in 1995, AstraZeneca began simultaneously lowering ASP and raising AWP for Zoladex. The spreads in Figure 3 corroborate the practices to which AZ pled guilty, practices designed to compete with Lupron. The fraudulent promotion of selling free samples and other price offsets began in 1993. Hence, as noted by *MedPAC* (¶ 22-24 above), the spread was being increased through the two blades of the scissors – intentional reduction of the ASP (through price offsets and provision of free samples to sell) and intentional inflation of the

AWP. These observed spreads are consistent with the theory of competitive spread inflation, through which manufacturers responded to economic incentives by increasing the spread **to the benefit of providers and not to the benefit of either consumers or payors.** I note that the increase in the AWP for this NDC of Zoladex ends in 1999, at which time the majority of state Medicare Part B carriers had adopted a Least Costly Alternative (LCA) policy whereby reimbursement for Lupron and Zoladex would be reimbursed based on the AWP for the less costly of the two.<sup>58</sup> Since the least costly alternative was (and still is) Zoladex, this meant that any increase in Zoladex's AWP would increase the spread for **both** Lupron and Zoladex, thus eliminating the competitive impetus for AWP manipulation. While inflation of the AWP alone no longer provided incentives to move market share, the spread does not decrease. AZ could still strategically make use of its ASP, lowering it relative to its AWP, in order to effectively compete for market share relative to Lupron. AZ clearly understood these aspects of "Return to Practice" as demonstrated by this 1995 AZ internal memo:

“ ... [T]he Return to Practice that can be realized via the purchase of LHRH agonists is the primary driver behind this market. Return to Practice is enhanced by widening the margin between the published price and the acquisition cost. This can be accomplished through several pricing manipulations:

- 1) Increase the AWP
- 2) Decrease the acquisition cost relative to the AWP, or
- 3) Both 1 and 2.

In order to maximize the Return to Practice, and to maximize our competitive position, it is recommended that we exercise option #3 from above by implementing a differential price increase. .... Furthermore, in order to allow Zoladex to be competitive with Lupron in the top tier of accounts, it is recommended that we **create a discounted tier of 24% for purchases in excess of 192 depots (32 cases).** The net result of these two pricing actions is that purchases of Zoladex will result in a **more**

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<sup>58</sup> The LCA policy was adopted by HCFA carriers beginning in May 1997. South Carolina was the first to adopt it and in time it was adopted by almost all states.

**favorable Return to Practice than Lupron at all purchase volumes above 6 depots.”<sup>59</sup>**

42. AZ documents produced in discovery are substantial and confirm my opinion that AZ manipulated the AWP and/or the ASP to compete for market share with TAP’s Lupron as TAP manipulated the spread.

a) AZ explicitly recognized that Zoladex’s market share and profitability would be increased through spread manipulation:

- “The market we are in wants a more expensive Zoladex, because the doctor can make more money.”<sup>60</sup>
- “During 1996, the basic strategies that guided our promotional efforts for Zoladex included: 1) presentation of an improved economic profile to the direct purchasing urologist.”<sup>61</sup>

b) One memo explained, “Return to Practice” was essential in order to compete:

“ZENECA has learned that in order to compete in [the] market dominated by Medicare, there needs to be a compelling argument based on ‘total Return To Practice.’ It is on this basis that many Uroologists decide which LhRh agonist to use. ... Return To Practice is derived by adding the difference between Medicare reimbursement [based on AWP] and acquisition price, ... patient co-pay which equals the 20% deductible that Medicare does not pay, and the benefit of [certain volume discounts].”<sup>62</sup>

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<sup>59</sup> Internal Memorandum from Keith Patterson to Chris Iacono, November 20, 1995 regarding Zoladex Pricing Strategy, Plaintiffs’ Exhibit 133 (AZ0080407-11 at AZ0080409).

<sup>60</sup> See Plaintiffs’ Exhibit 132 (AZ0021838), October 12, 1995 Memo from Thomas Chen to Keith Patterson re: Price Increase for Zoladex.

<sup>61</sup> Plaintiffs’ Exhibit 69 (AZ0004616-38 at AZ0004633), Zoladex Strategic Summary 1998-2002.”

<sup>62</sup> Plaintiffs’ Exhibit 14 (AZ0237142-163, at AZ0237143), November 3, 1995 Memo from Market Strategy and Contract Operations and the Zoladex Marketing Team. The definition of Return to Practice as the spread between AWP and the actual acquisition cost to physicians is also confirmed in AZ deposition testimony (see Deposition of Christopher Waldo Bowman, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, October 13, 2005, pp. 37-38 and Deposition of Steven Strand, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, June 17, 2005, p. 66).

Deposition testimony further confirms that AZ used return to practice as one of its marketing strategies.<sup>63</sup>

- c) On November 3, 1995, AZ's Market Strategy & Contract Operations and the Zoladex Marketing Team recommended an 8.25% increase in AWP to create a 30% spread, "which leverages reimbursement" and "deliver[s] a per-unit Return To Practice in excess of what Lupron's current scheme can deliver."<sup>64</sup> The memo further recognized that AZ needed a compelling spread:
 

"Our campaigns to grow ZOLADEX sales based on product attributes and somewhat straightforward pricing strategies have continually been thwarted by TAP responses as well as the method used by Medicare to reimburse for LhRh agonists. Without rehashing the entire economic scenario, ZENECA has learned that in order to compete in market dominated by Medicare, there needs to be a compelling argument based on 'total return to practice.'"<sup>65</sup>
- d) This memo is part of a longer market strategy document emphasizing the profit motive incentivizing urologist/oncologist providers, which Zoladex sales representatives would review with urologists to increase sales of Zoladex

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<sup>63</sup> "Q. And so just to clear that up, you do agree that Zeneca did use return to practice as one of its marketing strategies with respect to Zoladex; is that right? A. Yes." (Deposition of Thomas Chen, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, Civil Action 01-CV-12257-PBS, December 14, 2005, p. 126).

"Q. At your initiative, did you ever discuss return with doctors during that time period [mid-90s]? A. I would imagine, I think it opened some doors for us when we had a new pricing structure. It was something that we can kind of go in and discuss with doctors on the pricing of Zoladex, so, yes." (Bowman Deposition, p. 44.)

"Q. And so after '98, you would still use the return to practice as one of the arguments for why a physician should purchase Zoladex as opposed to Lupron; is that right? A. Yes. Q. Did you ever stop using the return to practice as one of those arguments at any time? A. No." (Bowman Deposition, pp. 102-103.)

<sup>64</sup> Plaintiffs' Exhibit 14 (at AZ0237144), *op. cit.*. See also Chen Deposition (pp. 102-105). Even though it appears that this proposal was not accepted or enacted upon, it shows that AZ was exploring a variety of ways of increasing the spread.

I note in passing that while this increase to 30% was clearly motivated by the AWP Inflation Scheme, the yardstick threshold spread that I ultimately use for a determination of causation and damages (30%) would not produce a finding of liability in this example (see Section VII). My threshold would therefore be conservative for Zoladex at this suggested spread.

<sup>65</sup> Plaintiffs' Exhibit 14, *op. cit.* (at AZ0237143).

by showing the doctors “how much money the doctor or the office could save by purchasing one drug over the other.”<sup>66</sup>

“Market research as well as anecdotal trade reports are replete with mentions of Urology Networks forming in the marketplace. Physicians are banding together across states in order to vie for third party pay contracts as well as fend-off managed care attempts to force them to enter into deep discount agreements for patient care. As we have come to understand in our experience with ZOLADEX, Urologists are motivated by economics. Perhaps more so than any other medical specialty we have encountered. The higher volume discount now being offered by TAP positions Lupron as delivering a higher return to practice within these newly forming groups. Our campaigns to grow ZOLADEX sales based on product attributes and somewhat straightforward pricing strategies have continually been thwarted by TAP responses as well as the method used by Medicare to reimburse for LhRh agonists. **Without rehashing the entire economic scenario, ZENECA has learned that in order to compete in market dominated by Medicare, there needs to be a compelling argument based on ‘total return to practice’.** It is on this basis that many Urologists decide which LhRh agonists to use”<sup>67</sup> (emphasis added).

- e) AZ created Physician Buy Groups that could take advantage of higher volume discounts to create higher spreads and profits for Zoladex purchasers.

Initially, purchase groups were informal associations of urologists. As time went by, Buy Groups became part of AZ’s contract strategy, and members formally contracted with AZ.<sup>68</sup> It was these Buy Groups that were contractually required to maintain confidentiality<sup>69</sup> regarding price competition between TAP and AZ, as discussed in my ¶ 27.b) above.

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<sup>66</sup> Bowman Deposition, pp. 56-58.

<sup>67</sup> Memo from Market Strategy & Contract Operations, Zoladex Marketing Team, to Chris Iacono, November 3, 1995, Subject: ZOLADEX Pricing and Volume Discount Strategy, Plaintiffs Exhibit 14 (AZ0237142-163 at AZ0237143).

<sup>68</sup> Bowman Deposition, pp. 45-46, 70-71, 73.

<sup>69</sup> See Plaintiffs’ Exhibit 982U, *op. cit.*

- f) AZ understood what the AWP/ASP spread and Return To Practice meant and how it could be used to compete with Lupron.

"The single most important force behind the popularity of the LHRH agonists is their profitability, which is a direct result of Medicare reimbursement policy."<sup>70</sup>

"TAP has grown Lupron sales to approximately \$650 million with 80 percent to 90 percent of sales being in the prostate cancer market. They have achieved this goal through aggressive promotion that emphasized the profit potential from Medicare reimbursement. Medicare reimburses LHRH Analogs at Average Wholesale Price (AWP) minus 20 percent. Lupron has a higher AWP than Zoladex, therefore, the physicians have made greater profit margins for injecting Lupron than Zoladex. Commercial intelligence reports that TAP offer various incentive programs that enhances the profit potential for the physicians. The profit motive of the physicians has made it very difficult for Zeneca to compete effectively in this marketplace. The transition of Medicare patients into managed care will be a positive benefit for Zoladex as 'cost' instead of 'profit' will be of greater concern in this market. TAP will not relinquish this business easily, therefore, Zeneca will be forced to discount the price of Zoladex to fend off TAP."<sup>71</sup>

A Zoladex contracting strategy document shows that AZ recognized what return to practice is, they calculate return to practice and compare to Lupron [at AZ0427252-3]. In addition, "'Return to practice' favors ZOLADEX with most important customers"<sup>72</sup>

"[...] we have recently learned of a TAP 'bounty' program, whereby the TAP representatives were empowered to offer unrestricted grants (as high as \$10,000) to any account who had converted to Zoladex 10.8mg in return for switching back to Lupron 3-month depot."<sup>73</sup>

"Some non-users use Lupron because profit obtained from Medicare reimbursement is greater for Lupron than ZOLADEX."<sup>74</sup>

"Medicare reimbursement for LHRH injections allows urologists to make additional profits. TAP has capitalized on this situation by promoting Lupron's profit potential."<sup>75</sup>

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<sup>70</sup> "Zoladex Strategic Plan, 1996-2000, Patterson Exhibit 4, AZ0004734-55 at AZ 0004746.

<sup>71</sup> "Medicare Market Segment Strategic Plan, 1997-2001, Patterson Exhibit 5, AZ0022281-94 at AZ0022288

<sup>72</sup> Proposed Zoladex Contracting Strategy, Patterson Exhibit 6, AZ0427246-65 at AZ0427264.

<sup>73</sup> "Zoladex Strategic Summary 1998-2002" AZ0004662-84, Patterson Exhibit 20, AZ0428340.

<sup>74</sup> "Prostate Cancer Situation Analysis Review" AZ0092152-62, Patterson Exhibit 48, at AZ0092153.

g) It is my understanding that the methods to reduce ASP identified above would violate the False Claims Act and the federal antikickback statute, as described by the *OIG Compliance Program Guidance*.

### **3. Bristol-Myers Squibb (BMS)**

43. BMS's former Director of Marketing for Oncology, Christof Marre, testified that, in response to generic competition, BMS would offer pricing discounts contained in confidential contracts.<sup>76</sup> However, in keeping with the "industry standard," BMS would not lower WLP or AWP.<sup>77</sup> BMS would employ this pricing strategy with each of its drugs that lost exclusivity.<sup>78</sup>

44. Although BMS acknowledges that "AWP is the most common reimbursement mechanism used in the marketplace," it also states that "BMS does not set AWP for its products. Third parties set AWP based on company labeler code and wholesaler surveys."<sup>79</sup> BMS has admitted that it directed the Red Book to change the mark-up factor on BMS oncology drugs from 20.5% to 25%,<sup>80</sup> and Red Book did so.<sup>81</sup> In addition, because AWP is directly related to WAC (WLP), whenever BMS reported a WAC price to these publishers they were in effect setting the AWP. BMS's response to an interrogatory explains this process:

"Generally speaking, there is a multi-step information flow between BMS and the above publications [Red Book, First DataBank, and MediSpan]. In 'Step 1,' someone from the finance department within BMS sends to

<sup>75</sup> *Ibid.*, at AZ0092154.

<sup>76</sup> See Marre Deposition, pp. 40-41.

<sup>77</sup> *Ibid.*, pp. 85-87.

<sup>78</sup> See the graphs below for each BMS drug. See also *ibid.*, pp. 85-87, 94 and 100-101 for specific deposition testimony regarding Blenoxane, Vepesid and Taxol.

<sup>79</sup> See BMS/AWP/00986726.

<sup>80</sup> See BMS/AWP/0011247-8 and Affidavit of Denise M. Kaszuba, Plaintiffs' Exhibit 184.

<sup>81</sup> See BMS/AWP/0011247-8.

the ‘Pricing Administration’ department either a price on a new drug or a price increase on an existing drug ... In ‘Step 2,’ Pricing Administration inputs the information into the BMS internal computer system. In ‘Step 3’ customers are notified of the new prices. ... In ‘Step 4’ the publications are notified. ... In ‘Step 5’ the publication generally sends a ‘report’ back to BMS demonstrating what it has done with the information BMS has provided. Such reports usually show the WLP/DLP and AWP.”<sup>82</sup>

Clearly BMS recognizes that, as a matter of economics, list prices are some of the most important signals that all drug manufacturers, particularly innovator drug manufacturers, use to strategically place drug products in the market. The two most important list prices are the AWP and the WAC (or WLP). Since there is a well understood formulaic relationship between AWP and WAC, reporting *either* to the price reporting services implies that *the other list price is set automatically*. AWP and WAC are “interchangeable” since the two list prices are usually related by a constant ratio and convey the same information to purchasers and other entities that rely on published price data.

45. BMS understands that AWP affects “the way that customers view the cost of our products.”<sup>83</sup> And BMS clearly understood that “[m]ost payers use AWP as a basis for calculating allowables.”<sup>84</sup>

### **3.A. Bristol-Myers Squibb: Blenoxane**

46. Blenoxane (bleomycin sulfate) is a chemotherapy drug for cancer including lymphomas and testicular cancers. The first generic manufacturer of bleomycin sulfate entered the market in 1996. It is interesting to note that the first generic AWP was almost identical to the

<sup>82</sup> BMS Response to Interrogatory 5, January 19, 2004 (Plaintiffs’ Exhibit 178).

<sup>83</sup> See BMS/AWP/01109782.

<sup>84</sup> “Extending & Enhancing Lives: Practice Efficiencies and Quality Care Workshop” Plaintiffs Exhibit 222 (BMS/AWP/001502304-38 at BMS/AWP/001502312).

Blenoxane brand AWP.<sup>85</sup> The generic AWPs were not lower than the brand AWP until other generic manufacturers entered the market in 2003.

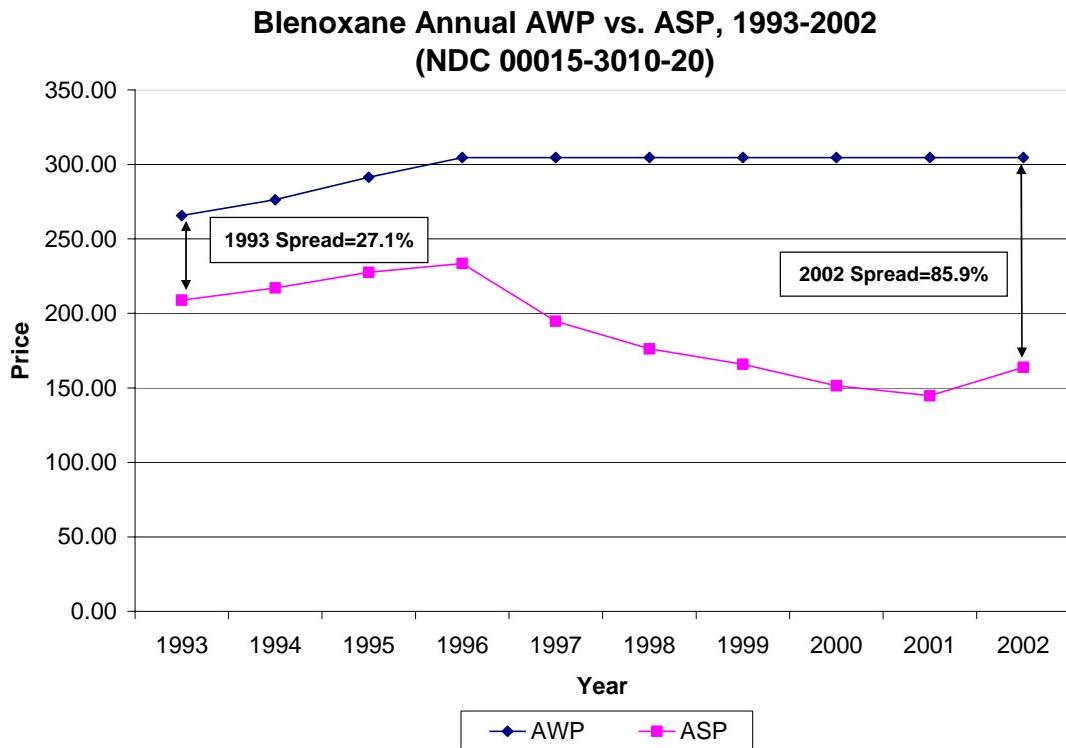
47. In response to generic competition, BMS began to reduce the ASP of Blenoxane relative to the AWP in 1996 and continued to do so through 2001, thereby substantially increasing its spread to physicians. Strategic pricing materials reviewed during discovery summarize these ASP reductions. For example, a memo from M. Barnard to G. Seymour, dated January 10, 2003, summarizes the discount at 61-62% off of WLP (or WAC) for the 15 mg dosage and 65-66% for the 30 mg dosage for the 3rd and 4th quarters of 2002.<sup>86</sup> For the NDC shown in Figure 4, Blenoxane's spread started at 27.1% and reached as high as 110.3% in 2001, before declining to 85.9% in 2002.<sup>87</sup>

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<sup>85</sup> The AWP for Blenoxane (NDC 00015-3010-20) was \$304.60 in 1998, compared to the first generic competitor Pharmacia & Upjohn (NDC 00013-1616-78) with an AWP of \$309.98 in that same year.

<sup>86</sup> BMS/AWP/000071159-62.

<sup>87</sup> See Attachment G.2.c for a complete table of Blenoxane spreads over time.

**Figure 4:**

### **3.B. Bristol-Myers Squibb: Taxol**

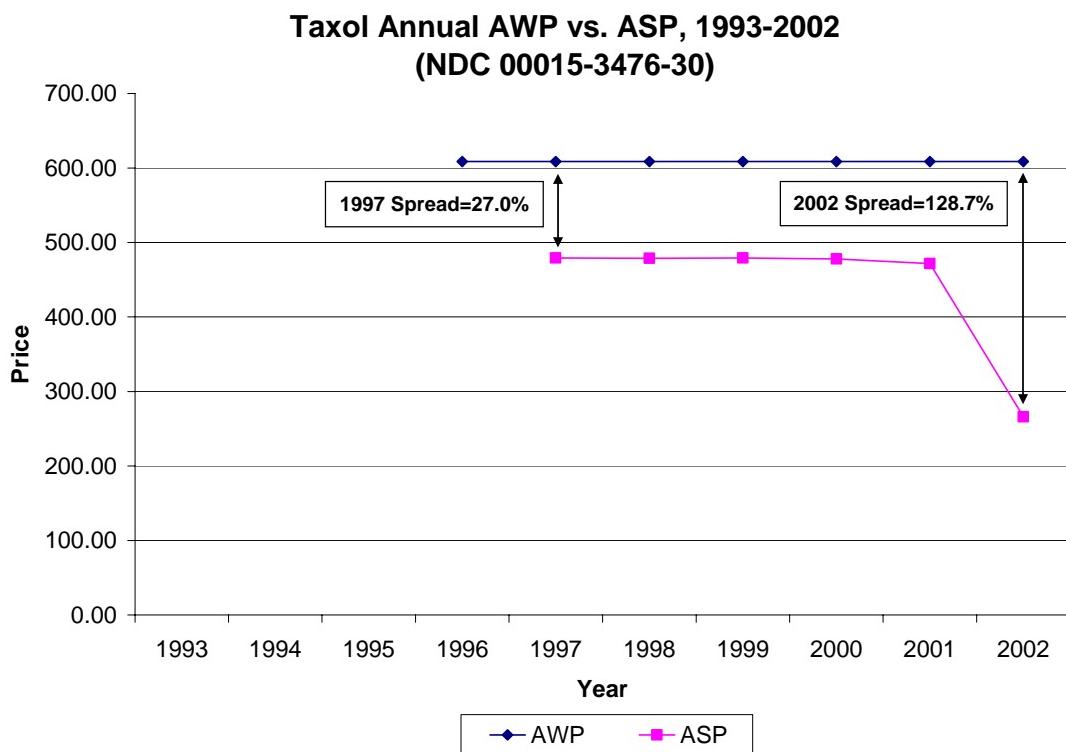
48. Taxol (paclitaxel) is a cancer medication used primarily in the treatment of breast, ovarian and lung cancer. BMS launched Taxol in 1992 as the first drug in the “taxane” category. While Taxol enjoyed exclusivity (through 2001), BMS maintained a spread below 30%. Specifically, when it launched, using RedBook AWPs, its spread was 25% and remained at 25-27% from 1994 until 2000, when generic launch introduced price competition to move market share. Using First DataBank’s AWPs, the spread upon launch was 20% and remained at 21-22% from 1994 until 2000. In November 2000, Ivax entered the market with its licensed brand paclitaxel product, Onxol. Additional generics entered the market in 2001. In response to

generic competition in 2001, Taxol decreased its ASP to providers by approximately 25-50%.<sup>88</sup>

This pattern is presented in Figure 5.

49. In one internal document, BMS begins to contemplate discounts in response to generic entry. It is recognized that with Taxol, they “want market share” and they “can’t realize it fast enough with medical literature and sales force” and they “can gain more share points by discounting...”<sup>89</sup> Indeed, after paclitaxel generics came to market, BMS responded by offering significant discounts, and it did not change AWP.<sup>90</sup>

**Figure 5**



<sup>88</sup> BMS reduced Taxol’s ASP to providers from \$471.62 in 2001 to \$266.14 in 2002 (44% decrease) for NDC 00015-3476-30 and reduced the ASP from \$141.65 in 2001 to \$108.64 in 2002 (23% decrease) for NDC 00015-3475-30 (as shown in the graph above). See Attachment G..2.c for other Taxol spreads.

<sup>89</sup> “Taxane Economics: Effect of Dose and Schedule” Plaintiffs’ Exhibit 221 (BMS/AWP/000157423-35 at BMS/AWP/000157434).

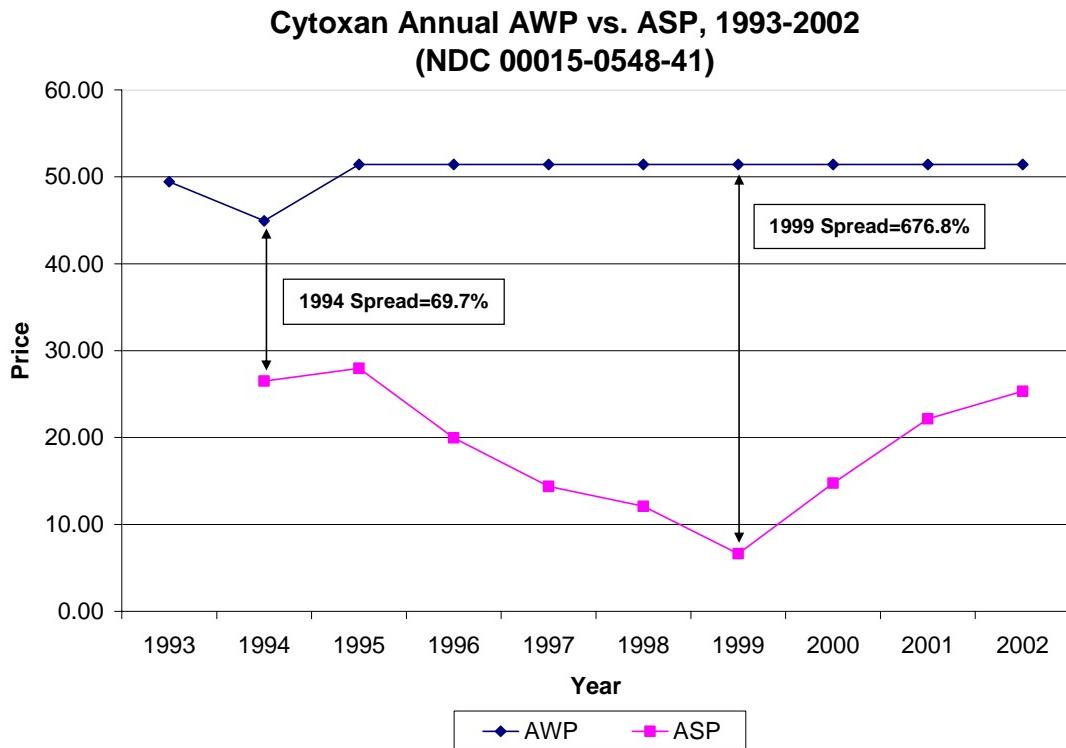
<sup>90</sup> See Marre Deposition. 40-41, 100-01.

***3.C. Bristol-Myers Squibb: Cytoxan***

50. Cytoxan (cyclophosphamide) is an alkylating agent used to treat cancer of the ovaries, breast, blood and lymph system, and nerves. BMS markets Cytoxan in both an injectable and tablet form. The injectable form has been subject to generic competition throughout the Class Period, while a generic version of the tablets did not enter the market until 2000.<sup>91</sup> As evident in Figure 6 below, BMS has consistently sold injectable Cytoxan at ASPs significantly lower than the listed AWP, thereby offering substantial spreads to incentivize physicians. Cytoxan's spreads frequently exceeded 100% and reached over 500% in certain years (see Attachment G.2.c for the complete table of Cytoxan spreads).

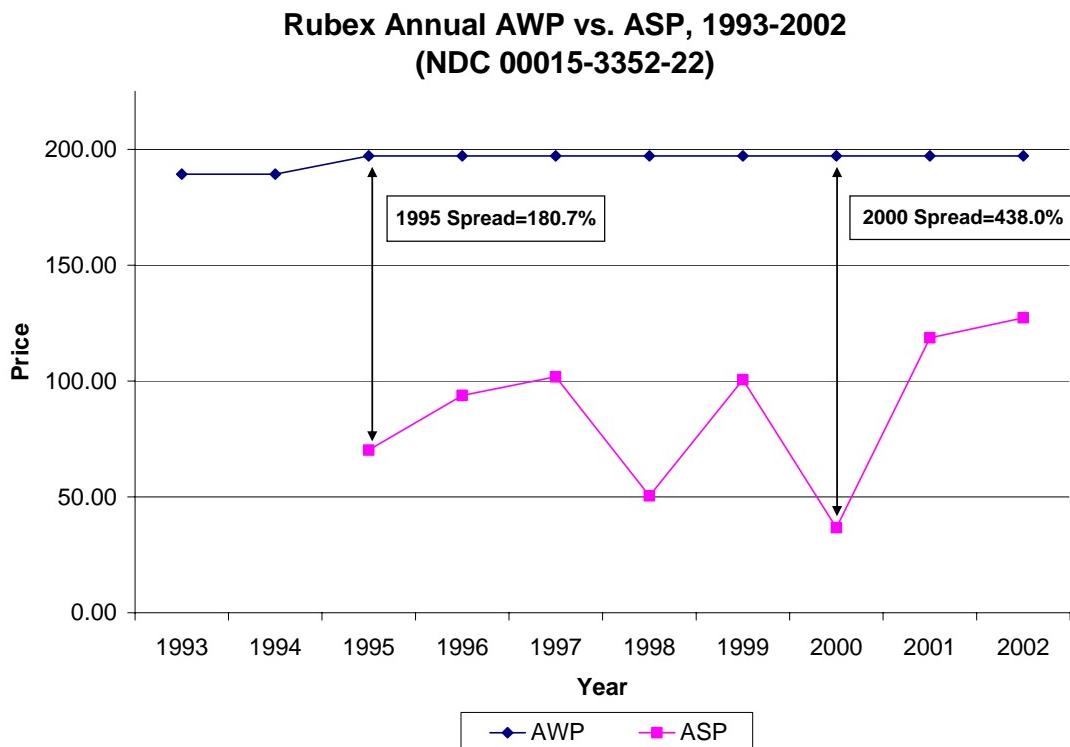
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<sup>91</sup> Note that the increasing ASP from 1999 to 2002 appears to be a result of BMS offering fewer contract discounts as generics began to exit the market due to difficulties in the manufacturing process. See Marre Deposition, pp. 88-90.

**Figure 6:**

### **3.D. Bristol-Myers Squibb: Rubex**

51. Rubex (doxorubicin) is an antineoplastic used to treat multiple types of cancer, including cancers of the blood, lymph system, bladder, breast, stomach, and others. BMS has marketed the product since 1993, and as can be seen in Figure 7, marketed on spread for most of the period (spreads in excess of 400%). This is consistent with BMS's contract discounting strategy for Rubex.

**Figure 7:**

### **3.E. Bristol-Myers Squibb: Vepesid**

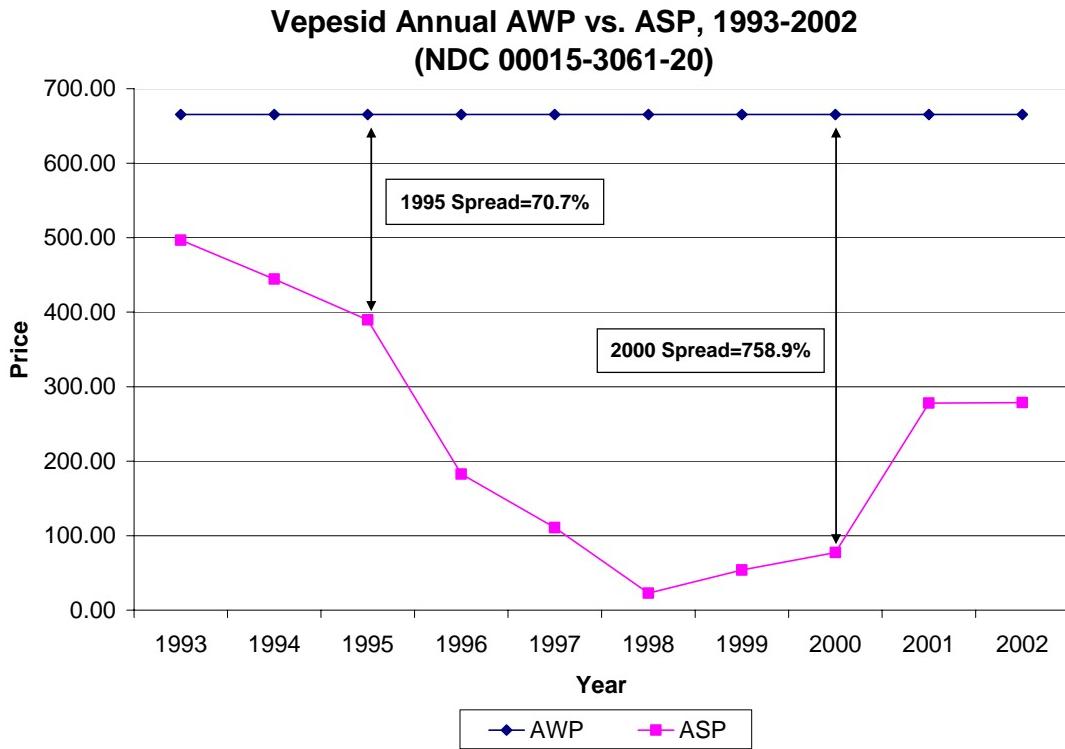
52. Vepesid (etoposide) is used in the treatment of cancer of the lung or testicles. Etoposide acts by interfering and slowing the growth of cancer cells and consequential spread within the body. Generic etoposide has been available since 1994 for the injectable form of the drug. In Figure 8, pricing strategies reflected in spreads for Vepesid (an injectable form) are found to have responded to generic competition in 1994. BMS reduced the ASP to providers, thereby increasing the spread in excess of 1000% in 1998 and 1999.<sup>92</sup> See Attachment G.2.c for

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<sup>92</sup> Deposition testimony also confirms that contract prices for Vepesid “deteriorated very massively” in response to generic competition. Also note that Mr. Marre recalls that “we weren’t always willing to continue matching those low prices,” thus explaining the increase in ASP after 1998. See Marre Deposition, p. 94.

a complete table of Vepesid spread data. It is interesting to note that the spreads on the tablets are usually less than those found for the injectable forms, since the IV forms are those targeted to providers who profit directly from the spread and can more effectively move market share.

**Figure 8:**



#### **4. Johnson & Johnson: Procrit and Remicade**

53. Procrit is a bone marrow stimulator used to treat anemia. It is therapeutically similar to EpoGen and Aranesp. Remicade is a TNF blocker used for autoimmune diseases such as rheumatoid arthritis.

54. Johnson & Johnson (as Ortho Biotech, OBI) understood the importance of profit as providers selected Procrit rather than alternative therapies.

“As Procrit’s market position continues to grow, pressure and attention to coverage and reimbursement will increase significantly, particularly for the oncology franchise ... Physicians tend to determine the source of Procrit ... and site of care depending on expected reimbursement outcomes. ... OBI must preserve positive economics for physicians”<sup>93</sup>

55. Johnson & Johnson explicitly recommended that sales personnel increase Procrit business by discussing profit with providers. In a 1996, memorandum, John Hess describes one strategy as follows:

“The ability to tactfully discuss how an office can profit from providing Procrit in the office. This discussion can be brought up whenever an office raises the objection about the expense of Procrit therapy and how they are at risk of losing money when they purchase expensive medications such as Procrit. The office needs to understand that there is profit associated with Procrit and that they are also protected from loss under our Reimbursement Assurance Program.”<sup>94</sup>

Mr. Hess goes on to show how to calculate a physician’s “return on equity” for purchasing and reimbursing Procrit and gives examples of “Non-Medicare per patient profit” as well as “Medicare per patient profit.” The memo also suggests that the sales personnel go through such an exercise using the provider’s own “real numbers” for acquisition costs by “[drawing] out the scenario on a piece of scratch paper.”

56. Johnson & Johnson likewise understood the importance of provider profit for its Remicade franchise. For example, Keith Patterson, a former Centocor Marketing Director, states:

“In the instance of rheumatoid arthritis, which was an elderly population, there was a component of return to practice that was included in our promotional emphasis. ... The acquisition price was lower than the reimbursed price, so that there was a spread, and that was illustrated to the physicians ... [by] [t]he sales representatives.” ... we did attempt to educate them [rheumatologists], but my

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<sup>93</sup> Strategies for Shaping the Reimbursement Environment, December 1999, Ortho-Biotech, Inc., Plaintiffs’ Exhibit 334 (MDL-OB10000/6781, 6789, 6810).

<sup>94</sup> Memo to Minneapolis District from John Hess, July 10, 1996, Plaintiffs’ Exhibit 268 (MDL-OBI0063656-57).

recollection was that there was a program called the Practice Enhancement Program. ... I don't remember the specific components, but it did include the financial incentives that could be realized through the reimbursement. ... A part – part of the incentive for – for physicians to begin using Remicade and infusing it in their office was the fact that they could make money by doing so.”<sup>95</sup>

57. Furthermore, Mr. Patterson characterized this marketing methodology as “a very similar manner to that which we have discussed for -- for Zoladex.”<sup>96</sup>

58. A 1997 Ortho Biotech memo acknowledges the “windfall” that physicians receive for Procrit and “It would be safe to assume that a decrease or loss of the windfall would impact some physician’s prescribing pattern for a drug.”<sup>97</sup>

59. In a July 6, 1999 memo, Centocor’s Senior Director for Reimbursement Services, Michael Ziskind, explains why it is critical to Remicade business to hide the spread between AWP and acquisition cost (emphasis added):<sup>98</sup>

“For example, if we were to routinely use cost to wholesalers we would set payers’ expectations too low. If we were to routinely use AWP, we might scare off some providers who are concerned about acquisition cost. My recommendation is to adopt some standard description so that the audience knows what ‘cost’ is being cited. I would not, however, include both cost figures in the same presentation *because that may highlight spread more than we would like....*”

60. The resulting spreads on Remicade are depicted in Figure 9.

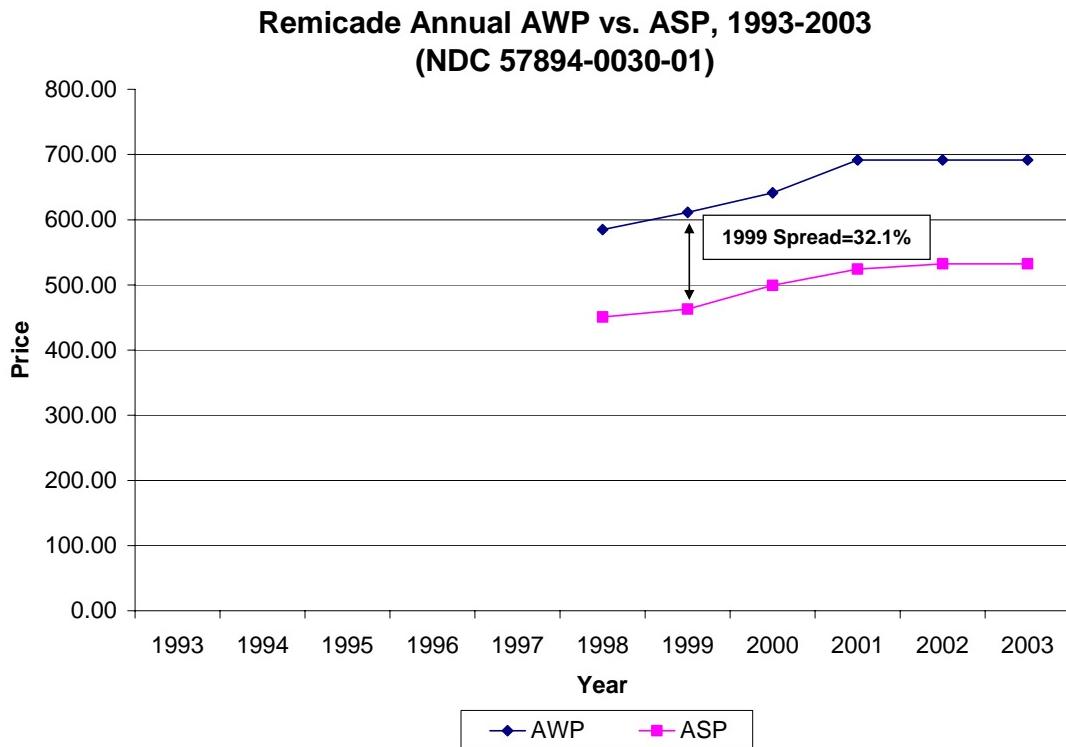
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<sup>95</sup> Deposition of Keith Patterson, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court of Massachusetts, MDL No. 1456, Civil Action 01-CV-12257-PBS, June 28-29, 2005, pp. 313-314, 316-317.

<sup>96</sup> See Patterson Deposition, pp. 311-313.

<sup>97</sup> An Ortho Biotech memo from M. Klein and C. Dooley to S. Salmon, April 3, 1997, Plaintiffs’ Exhibit 365 (MDL-OBI00061785).

<sup>98</sup> Memo to Jason Rubin from Mike Ziskind, July 6, 1999, Plaintiffs’ Exhibit 260 (MDL-CEN000085404-05).

**Figure 9:**

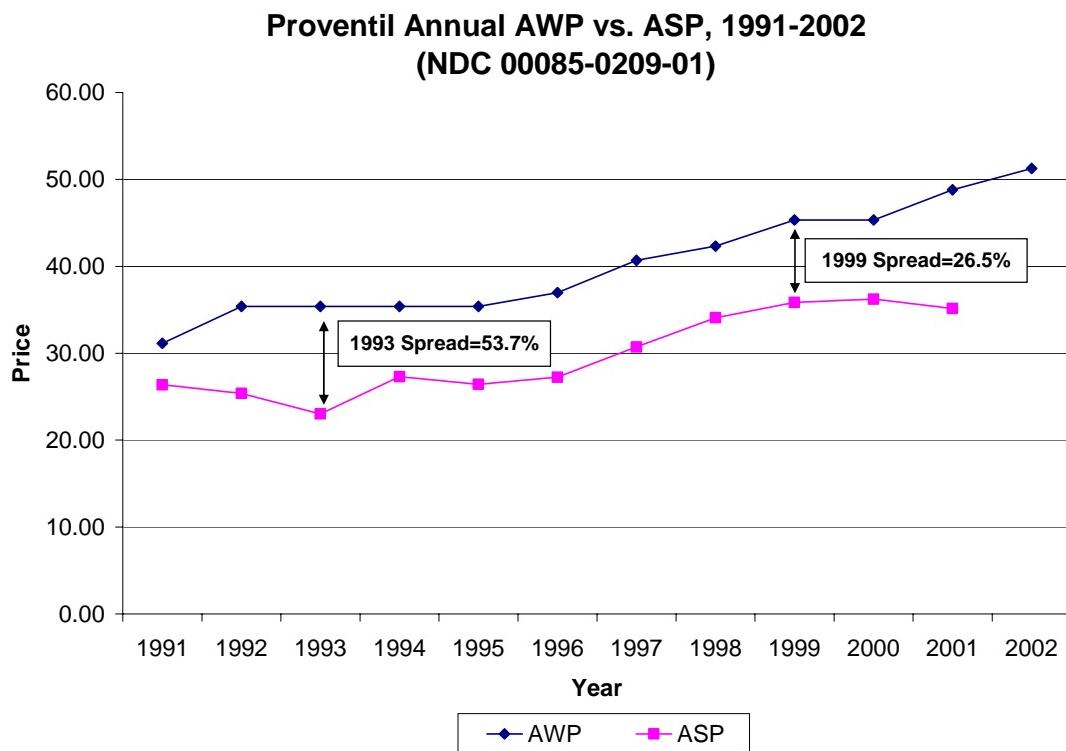
### **5.A Schering-Plough – Proventil and Albuterol Sulfate**

61. Schering-Plough has five drugs at issue in this case, one of which is Proventil. Spread information for a single NDC of Proventil is presented in Figure 10.
62. Schering-Plough launched Proventil (branded albuterol sulfate) prior to 1991, but has faced competition from generics and another brand during the Class Period. Schering's Proventil and GlaxoSmithKline's Ventolin are the two branded versions of albuterol sulfate, and have co-existed on the market during the Class period. The spreads for both of these brands have consistently exceeded 30%, reaching levels over 100% for select NDCs (see Attachment G.4.c). Proventil, Ventolin and all generic versions of albuterol sulfate are multi-source drugs subject to

reimbursement through J-Codes where reimbursement is determined by the lower of the median of generic AWPs of all NDCs in the J-Code and the lowest branded version of the drug in the J-Code. As discussed above in ¶¶ 32-33 above and depicted in Figures 1.A-1.C, the AWPs for albuterol sulfate cluster somewhat below the AWPs of the branded versions of the drugs (when the generics launched; see Figure 1.C) in what appears to be a tacit Nash Equilibrium. Throughout the Class Period, however, the AWPs of branded albuterol sulfate (Proventil and Ventolin) continued to increase after generic launch (see Figure 1.C). Reimbursement in this case would be determined by the median of the cluster of generic versions, which was the same level of reimbursement for all versions of albuterol sulfate, generic and branded alike within the J-Code. The median price did not change much once generics launched (it did increase some per extended unit; see Figure 1.C); it remained near the level characterizing branded and generic AWPs at the time of generic launches. The apparent Nash-equilibrium clustering over time seems to reflect the attempt to maintain the generic-based reimbursement level as high as possible for this chemical compound (albuterol sulfate), relative to therapeutic competitors. All spread competition among alternative producers of albuterol sulfate has therefore occurred through manufacturers reducing their ASPs relative to the fixed median AWP. While inflation of the generic AWPs would have occurred with and been relatively fixed at the generic launch (as some percentage off Proventil's AWP), the later reduction of ASPs to implement spread competition is still economically injurious to consumers and payors in the following sense. Price competition occurs among generic drug manufacturers, none of which benefits consumers and payors. Instead, providers' profits are increased while payors' and consumers' reimbursement rates remain the same. This is not the paradigmatic version of pro-consumer price competition, as clarified in ¶¶ 26-35 above.

63. Indeed, for all multi-source drugs for which the median generic AWP within a J-Code is relatively stable over time, ASP-competition is similarly pro-provider rather than pro-consumer. In precisely the same way as occurs with single-source physician-administered subject to AWP inflation and ASP reduction, the result with multi-source physician-administered drugs is that spread competition is aimed at moving market share by increasing the profits of providers, not reducing the costs to consumers and payors.

**Figure 10:**



**5.B: Schering-Plough – Intron A**

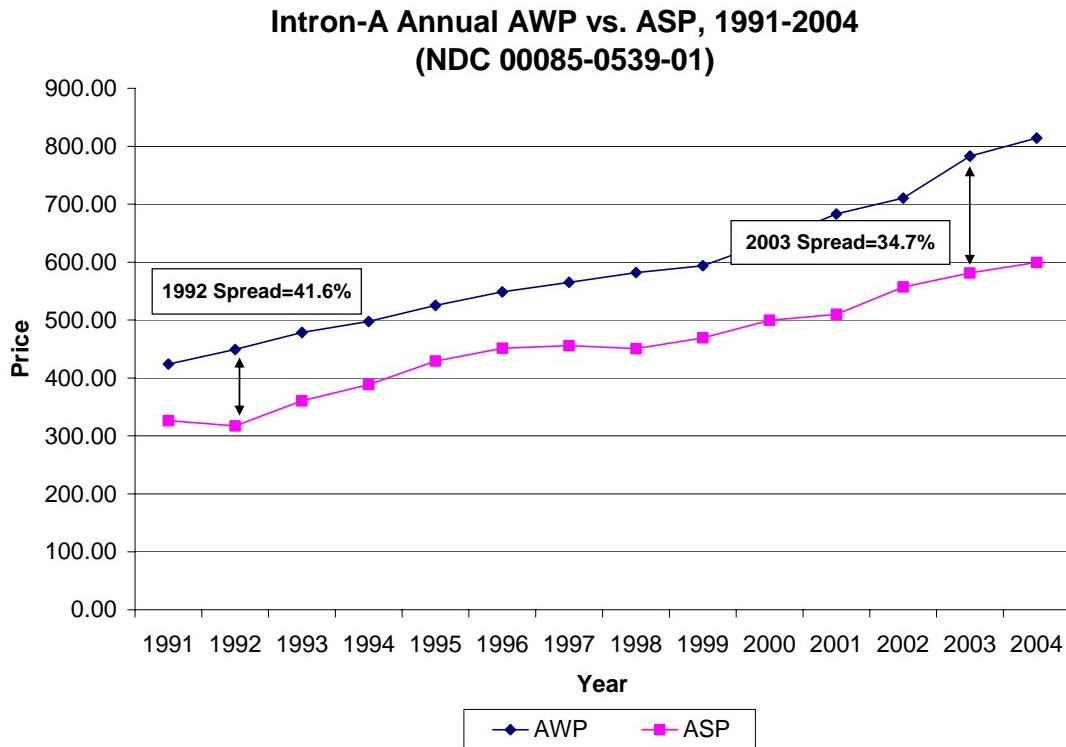
64. As evident in Figure 11, both the AWP and the ASP for a given NDC of Intron A increased over time, with relatively high spreads throughout. Examples of spreads for Intron A in Figure 11 include 41.6% in 1992 and 34.7% in 2003, confirming that the acquisition cost to physicians for Intron A was lower than the AWP throughout the Class Period.

65. A Schering Plough email describes the “Price advantages in setting up Direct Account through Schering representative.” The document compares the Net Direct price with the amount reimbursed for J9214 at 95% AWP.

“Attached are the new 95% of AWP reimbursements for our Urologists, Oncologists, using Intron A for Bladder Cancer. Treating bladder patients with Intron is still very profitable. One patient on Intron can represent \$16,956.36 of incremental sales and \$2,373.84 of profit for our physician just on the drug alone. These figures are based on having your physician buy Intron at Net Direct pricing and treating on high dose of Intron (12weeks of 100mlu weekly then 50 mlu monthly for 1 year). As you know this dose is very tolerable when given intravesically.”<sup>99</sup>

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<sup>99</sup> Email from David Maya RE: Intron 95% AWP reimbursement for Bladder, February 2, 1998, Plaintiffs’ Exhibit 394 (SPP0104510-12).

**Figure 11:**

#### 6. *GlaxoSmithKline: Zofran and Kytril*

66. While GlaxoSmithKline (GSK) is no longer a Defendant in this litigation, selected quotes from their discovery materials summarize the importance of return to practice and relative spreads for competition in this industry. Kytril and Zofran are anti-nausea medications used with chemotherapy, radiation or post surgery. While they have no generics, they are therapeutically similar and compete with one another.<sup>100</sup> Zofran entered the market in 1991 and Kytril in 1994. Example of spread competition from GSK discovery materials include the following:

<sup>100</sup> Anzemet is another brand name drug that also competes with Kytril and Zofran.

- a) "Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP. The typical spread between the List Price and the AWP in the industry is either 16 2/3% or 20%. The majority of agents in the oncology market carry a 20% AWP. This allows the oncologist to be compensated for the cost of the intravenous drug administered as Medicare reimburses at 80% of AWP. The administration of intravenous agents in the outpatient or clinic setting is almost exclusive to the oncology practice. SKB's clinic promotion has been based on a therapeutic equivalency campaign with significant reimbursement advantages in favor of Kytril. The current reimbursement spread favors Kytril at \$18.80 per single dose vial compared to Zofran at \$-0.89 per 32mg dose per patient. ... Because Kytril is available in a single dose prescription, the complete vial may be billed for reimbursement. Zofran, as a multi-dose prescription, may only be billed on a milligram basis for the dose administered. Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement."<sup>101</sup>
- b) "Moving forward we acknowledge the need for identifying strategies for continued and enhanced product growth. Our target customers are a small group of easily identified physicians, nurses, pharmacists, distributors, etc." (at GSK-MDL-KY01-008046). ... "Prior to the introduction of Zofran in February, 1991, 70% of chemotherapy was administered on an inpatient basis. In spite of there being no breakthroughs in development of anti-neoplastic therapies, there has been a significant shift toward outpatient treatment ... The trend toward outpatient administration has created many new variables in the marketing equation for chemotherapy-associated products: 1. Office claims administrators are playing an increasing role in drug selection between two therapeutically equivalent products based on financial implications. In the hospital, drug cost is a key factor in product selection because reimbursement is based on a fixed price DRG, and drug cost directly competes with the profit flow to the hospital. **In the outpatient setting, profit reflects the reimbursement allowance less the cost of the drug. So claims administrators are focused on maximizing that difference between reimbursement and cost.** To the extent a product has no or delayed reimbursement by payers, that product will not likely be used particularly if the competing product is covered. Zofran is fully covered. Kytril is gaining coverage but has significant hurdles primarily government bureaucracy which precludes its unconditional acceptance in the outpatient setting" (emphasis added).<sup>102</sup>

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<sup>101</sup> Memo from D. Cory to S. Strotzky, dated 10/31/94, Subject: Pricing Committee Recommendation, GSK-MDL-ZN-01-048606-9.

<sup>102</sup> US Marketing Strategic Plans, 1995-1997, SmithKline Beecham Pharmaceuticals, GSK-MDL-KY01-008042-59.

- c) “Effective March 7, 1996 Glaxo increased the Wholesale Acquisition Cost (WAC) and Average Wholesale Prices (AWP) of Zofran 4.9%. At the same time, Glaxo also increased their rebate to keep the Actual Acquisition Cost (AAC) of Zofran the same. What this means is that **Glaxo has increased the profit potential for physicians** by raising the amount that physicians should bill for the drug and by keeping the cost the same” (emphasis added).<sup>103</sup>

## IV. THE CALCULATION OF DAMAGES FOR CLASS 2

### A. Overview

67. I understand that one of the issues pending before the Court is to define what AWP means under the statutes and regulations passed by Congress. I understand the Court may adopt the “plain meaning rule,” and that published AWPs and the Medicare reimbursement rates derived from those AWPs are to be reported in accordance with either the *OIG Compliance Program Guidance* or with the *MPDIMA* guidelines, or with the application of the principles found in these two sources for the calculation of the drug acquisition costs of providers. I have been instructed by Counsel to proceed with this understanding. I assume that the “plain meaning rule” will require application of either set of guidelines in order to estimate the average drug acquisition cost of providers. Taking that interpretation as my point of departure, it is my opinion that the published AWPs, or the relevant percentages of those AWPs (95% and 85%, in accordance with footnote 46 above) for each Defendant did not meet that “plain meaning rule” when reimbursement rates calculated according to the Medicare statutes exceeded the ASP. Under the “plain meaning rule,” I understand that if this difference is positive, injury has been demonstrated and the extent of the damages quantified.

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<sup>103</sup> Letter from B. Boate, Kytril Special Projects, 3/11/96, GSK-MDL-KY01-007599.

68. If the Court defines AWP to be a published price that reflected all discounts, rebates and price offsets offered by a manufacturer to all non-governmental entities (*i.e.*, AWP was to conform to the *OIG Compliance Program Guidance* or the *MPDIMA*), the reported AWP would be (approximately) the ASP on all units sold ***to all non-governmental entities***.<sup>104</sup> Alternatively, if the Court defines AWP to be a published price that reflected all discounts, rebates and price offsets offered by a manufacturer to providers of the physician-administered drug (*i.e.*, AWP was to conform to the *OIG Compliance Program Guidance* and the *MPDIMA* for all units sold to the relevant providers), the reported AWP would be (approximately) the ASP on all units sold ***to all relevant providers***.<sup>105</sup> In either case, the injury to members of Class 2 is determined formulaically as the difference between the reimbursement rate based upon some percentage of the published AWP (as determined in footnote 46 above) and the relevant ASP. However, for my analysis I have interpreted the “plain meaning” rule with somewhat greater nuance, which I clarify through a discussion of reimbursement for single-source drugs.

- a) Over the period 1991 through 1997, 100% of AWP was the basis for reimbursement of single-source physician-administered drugs. By the “plain meaning rule,” therefore, the AWP should have been a reliable measure of the average acquisition cost of providers, *i.e.*, the providers’ ASP, taking into account all price offsets clarified by *OIG Compliance Program Guidelines*. To the extent that AWP exceeded the ASP, by the “plain meaning rule,” reimbursement by Medicare carriers was too

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<sup>104</sup> My reading of the recent *MPDIMA* suggests that CMS defines ASP in this fashion; see footnote 3.

<sup>105</sup> This definition of ASP would accord most closely with the notion of cost-based reimbursement under Medicare, since this measure of ASP would reflect the acquisition costs of providers, rather than the overall average acquisition costs of all users. This definition makes most sense as a matter of economics. Use of this definition of ASP **will produce the smaller measure of damages**, since ASPs calculated under this definition will be higher than under the one for all users. For my analysis here, I make use of the ASP as it relates to providers as the “plain meaning rule.”

high, on average, and Medicare was impacted and injured, on average, for all claims reimbursed.

- b) Over the period 1998 through 2003, 95% of AWP was the basis for reimbursement of single-source physician-administered drugs. By extension of the “plain meaning rule,” I assume that 95% of AWP should have been a reliable measure of the average acquisition cost of providers, *i.e.*, the providers’ ASP, taking into account all price offsets clarified by *OIG Compliance Program Guidelines*. To the extent that 95%\*AWP exceeded the ASP, by my extension of the “plain meaning rule,” reimbursement by Medicare carriers was too high, on average, and Medicare was impacted and injured, on average, for all claims reimbursed.
- c) During the year 2004 in which CMS transitioned to ASP-based reimbursement, x% of AWP was the basis for reimbursement of single-source physician-administered drugs, where x% is determined by the specific drug (it ranges from 80%-95%, with the majority being 85%; see footnote 46). Again, by extension of the “plain meaning rule,” I assume that x% of AWP should have been a reliable measure of the average acquisition cost of providers, *i.e.*, the providers’ ASP, taking into account all price offsets clarified by *OIG Compliance Program Guidelines*. To the extent that x%\*AWP exceeded the ASP, by my extension of the “plain meaning rule,” reimbursement by Medicare carriers was too high, on average, and Medicare was impacted and injured, on average, for all claims reimbursed.<sup>106</sup>

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<sup>106</sup> I note in passing that in all cases this interpretation of the “plain meaning rule” is that in the but-for world, Medicare was to reimburse at the average acquisition cost of the drugs (to the providers). Had the AWP been equal to and continued to have been equal to the “weighted average wholesale price (or acquisition cost)” to providers (as asserted by the FDB in their promotional materials), there would have been no need for Congress to reduce the

- d) Interpretation of the “plain meaning rule” for multi-source reimbursement is analogous for the periods identified in footnote 46.

## B. Formulaic Methodology for Calculating Damages

69. As the Court states, for Medicare Part B drugs “the reimbursement rate is set by statute, not negotiation,” ... and “damages calculations will be largely formulaic.”<sup>107</sup>

70. More specifically, for single-source brand name drugs reimbursed by members of Class 2,

- a) Prior to 1992, Medicare carriers took the AWP to be the physicians’ estimated acquisition cost and reimbursed at AWP.
- b) From 1992 to 1997, reimbursement was set at the lesser of the estimated acquisition cost (“EAC”) or AWP.
- c) On January 1, 1998, reimbursement was changed to the lesser of (1) the billed charge on the Medicare claim form or (2) 95% of AWP. This practice continued through 2003. While the statutory language changed to the “lesser of the billed charge” or 95% of the AWP, the understanding of “the billed charge” was the EAC of the drug,

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reimbursement rate to 95% or 85% of AWP. The reduction to 95% and 85% reflects the growing awareness by Congress that the “plain meaning rule” was being violated by the drug manufacturers.

<sup>107</sup> At pp. 57-60 of the *Memorandum and Order*, Judge Saris states for Class 2: “Again, the common factual issues (as outlined in the previous section) predominate, in that the TPPs are required by contract to supplement Medicare drug co-payments. Some TPPs may have greater sophistication with respect to the existence of spreads because they purchase self-administered drugs, but there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs. In any event, the reimbursement rate is set by statute, not negotiation. Therefore, there appear to be no factual differences with respect to reliance or causation that predominate over the common issues. Defendants have not pressed an extensive predominance challenge in this context regarding factual issues. ... Rather, defendants challenge class certification with respect to these TPPs primarily on the ground that the legal differences among the state consumer protection statutes predominate over the common legal questions. ... [As a result], the Court will certify a statewide class of TPPs that pay supplemental insurance covering Medicare Part B co-payments under Mass. Gen. Laws ch. 93A.”

despite the fact that 95% of AWP was used systematically to determine reimbursement.<sup>108</sup>

- d) From January 1, 2004 through December 31, 2004, drugs were generally reimbursed at 85% of AWP, with exceptions clarified in footnote 46.

71. For multi-source drugs reimbursed by members of Class 2, there is greater nuance (see footnote 46). Specifically,

- a) Prior to 1992, reimbursement was set at the AWP which was taken as the measure of the EAC.
- b) From 1992 through 1997, reimbursement was set at the lower of EAC or the average wholesale price defined as the median of the AWPs of all generic forms of a drug.
- c) On January 1, 1998, reimbursement was changed to the lower of the billed charge or 95% of an average wholesale price defined to be the lower of the median of the AWPs of all generic forms of a drug or the AWP of the least expensive brand-name drug.<sup>109</sup>
- d) From January 1, 2004 to through December 31, 2004, reimbursement was changed to 85% of an AWP defined to be the lesser of the median AWP of all generic forms of the drug or biological or the lowest brand name product AWP.<sup>110</sup>

72. By the “plain meaning rule,” I interpret these statutory changes as follows. I understand that the amount allowed for reimbursement was intended to be equal to EAC = ASP

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<sup>108</sup> See footnote 15 above.

<sup>109</sup> This interpretation (from footnote 46) is further confirmed in DHHS, HCFA Program Memorandum Intermediaries/Carriers Transmittal No. AB-00-110, November 14, 2000 and Transmittal AB-00-117, November 30, 2000. At pages 14-16 of the *Memorandum and Order*, Judge Saris appears to have slightly misstated the statute with respect to multi-source drugs for the 1998-2003 period.

<sup>110</sup> Judge Saris makes no mention (at p. 15 of the *Memorandum and Order*) of a change in reimbursement procedures for multi-source drugs beginning in January 2004.

over the period 1991-2004. The variation of the amount allowed as reimbursement and its relationship to AWP over time produces the following formulaic measures of Overcharge Damages per unit reimbursed by members of Class 2.

a) For Medicare single-source Part B drugs:

- Overcharge = (AWP – ASP) for 1991-1997;
- Overcharge = (95%\*AWP – ASP) for 1998-2003; and
- Overcharge = (x%\*AWP – ASP) for = 2004, where x% is determined by the specific drug; it ranges from 80%-95%, with the majority being 85%.<sup>111</sup>

b) For Medicare multi-source Part B drugs:

- Overcharge = (AWP – ASP) for 1991;
- Overcharge = (Median generic AWP – ASP) for 1992-1997;
- Overcharge = (95%\*Minimum{Median generic AWP, lowest branded AWP} – ASP) for 1998-2003;
- Overcharge = (x%\*Minimum{Median generic AWP, lowest branded AWP} – ASP) for 2004, where x% is determined by the specific drug; it ranges from 80%-95%, with the majority being 85%.

Note that for all cases, I take 20% of the amount of the difference between the amount allowed and the amount that should have been allowed under the “plain meaning rule,” since that is the coinsurance covered by the members of Class 2 under Supplemental Medicare Coverage.<sup>112</sup> Note also that in 2005, Congress set reimbursement based upon ASP. I do not calculate damages for Medicare Part B for 2005, since in that year it returned to an explicit cost basis.

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<sup>111</sup> Recall from footnote 46 that the relevant AWPs and ASPs are those of April 1, 2003.

<sup>112</sup> Class 2 private third-party payers are one type of payer that covers the Medicare coinsurance. The 20% Medicare coinsurance generally is paid by one of three groups of payers, including out-of-pocket Medicare beneficiaries (Class 1), Medicaid (excluded from my analysis) and private third-party payers (Class 2). According to Eppig and Chulis, private third-party payers account for approximately 69% of the Medicare coinsurance payments (see F. J. Eppig and G. S. Chulis, “Trends in Medicare Supplementary Insurance: 1992-1996, *Health Care Financing Review*, Vol. 19(1), Fall 1997).

73. The units subject to reimbursement need to be calculated. I discuss how this calculation is performed in Section IX below, which addresses Technical Issues. Likewise, reimbursement rates are calculated by J-Code. I discuss the necessary crosswalk between J-Codes and NDCs in the Technical Section IX.

### C. The Damage Calculations

74. For each remaining Track One Defendant, I have calculated the ASPs to providers and gathered data on the AWPs required to determine damages. I calculate damages as  $k * AWP - ASP$  for Class 2 (where  $k$  is described as above). The aggregate Class-wide damages are summarized below in Table 2.<sup>113</sup> The back-up for these Tables is provided in Attachments J.

**Table 2.A: Summary of Damages (Nominal \$)**

<b>Class 2: Medicare Damages to Third-Party Payors (Nominal \$)</b>		
<b>Company</b>	<b>National</b>	<b>Massachusetts</b>
AstraZeneca	\$180,882,758	\$4,781,279
Bristol-Myers Squibb	\$137,262,718	\$3,628,269
Johnson & Johnson	\$184,618,460	\$4,880,025
Schering-Plough	\$154,214,957	\$4,076,368

**Table 2.B: Summary of Damages (2006 \$)**

<b>Class 2: Medicare Damages to Third-Party Payors (2006 \$)</b>		
<b>Company</b>	<b>National</b>	<b>Massachusetts</b>
AstraZeneca	\$264,456,743	\$6,990,393
Bristol-Myers Squibb	\$235,559,906	\$6,226,562
Johnson & Johnson	\$258,043,574	\$6,820,873
Schering-Plough	\$250,944,878	\$6,633,233

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<sup>113</sup> Damages to Massachusetts are calculated using the percentage of retail prescription sales reported by state by Verispan.

**V. THE EVOLUTION OF MARKET KNOWLEDGE AND EXPECTATIONS  
REGARDING AWP AS A RELIABLE SIGNAL FOR COST:  
WHAT MEDICARE KNEW**

75. Much discussion in this matter has addressed what payors knew, when they knew it, how that information was revealed to them, and how they revealed their understanding of that information through observable behavior. Defendants have primarily directed this to the TPP members of Class 3. Since most private third-party payors follow Medicare's reimbursement practices and procedures with regard to physician-administered drugs,<sup>114</sup> it is useful to examine the response of Medicare and its carriers<sup>115</sup> to evolving information concerning reimbursement for and acquisition cost of physician-administered drugs. Indeed, the responses of HCFA, CMS and the Medicare carriers over time provide a natural experiment for revealing what they believed provider drug acquisition costs systematically were relative to the basis for reimbursement, the AWP.

76. Defendants have argued that HCFA and Medicare knew that AWP exceeded EAC and ASP and that they were aware of survey evidence that AWP exceeded EAC and ASP, at times "substantially." As a result, Defendants have asserted that HCFA and Medicare were not deceived by the particular instances of Defendants' alleged abuse of the AWP system through AWP inflation schemes, and that HCFA and Medicare had the information, ability and duty to mitigate the reimbursement impacts of Defendants' particular abuses of the AWP system.

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<sup>114</sup> Medicare Payment Advisory Commission, (MedPAC), Report to the Congress, Variation and Innovation in Medicare, June 2003 (hereafter, *MedPAC Report*). At page 16, the Report states: "MedPAC surveyed large private payers on their current payment rates for physician-administered drugs and any plans they have to change their payment formulas. Most private payers are still using AWP-based payment methods similar to the Medicare model." At page 166, the Report states: "Until recently, private payers devoted little attention to price and utilization of specialty drugs. Their payment systems, and the problems associated with them, have mirrored Medicare's AWP-based formula."

<sup>115</sup> Borrowing Judge Saris' characterization (PBMs at page 18 of her *Memorandum and Order*), in the context of reimbursement for physician-administered drugs, Medicare is the 800-pound gorilla.

77. In making these assertions Defendants have appealed to publicly available information developed by the Department of Health and Human Services (DHHS), the Office of the Inspector General (OIG) of DHHS, the General Accounting Office (GAO) and other academic and popular press research. To better understand their information content, I have compiled a list of these reports. I present that compilation in Attachment D to this testimony and summarize their findings. For my purposes here, note that only a subset of these studies present original survey information.<sup>116</sup> While even other studies could be added to this list, I believe this current list to be sufficiently representative.<sup>117</sup> From reviewing this list I conclude the following:

- a) **Many (33%)** of the OIG studies **focus upon self-administered drugs**, branded and generic rather than the drugs subject to this litigation.<sup>118</sup> These studies found that the average spreads on branded self-administered drugs through the end of the 1990s and after 2000 were, uniformly within my yardstick threshold<sup>119</sup> for a finding of causation and liability, which I develop more fully with my analysis of impact upon and damages to Class 3. Furthermore, these studies found that until the mid-1990s, the average spreads of generic self-administered drugs were, uniformly within my liability yardstick threshold. It was only in those surveys between 1996 and 2000 that the increased spreads on generic **self-administered** drugs became evident.

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<sup>116</sup> The other studies make use of data developed in this subset.

<sup>117</sup> I place greater weight on the information content of surveys, rather than newspaper and magazine articles.

<sup>118</sup> Twelve of the 36 studies focused on drugs covered by Medicaid and/or were dispensed through pharmacies; these drugs are for the most part, self-administered.

<sup>119</sup> As discussed below in Section VI, the value of that yardstick threshold is 30%.

- b) Approximately 44% of these studies focus upon physician-administered drugs, other than albuterol.<sup>120</sup> I relied upon two of them. In an attempt to look at trends over the decade, I identified one study implemented early in the Damage Period (the 1992 OIG report on chemotherapy drugs) and one study undertaken late in the damage period (the 2001 ASCO review of spreads on chemotherapy drugs and a prospective analysis of survey methods). Both reported spreads within my liability yardstick threshold for single-source physician-administered drugs.<sup>121</sup>
- c) For greater thoroughness, I present some survey results within these two end points and after 2001. I find that these additional studies support my findings.<sup>122</sup>
- The Bill Alpert article in Barron's (June 1996), undertakes original research of the top 20 Medicare drugs (in 300 dose forms), many of which were physician-administered drugs. Alpert finds spreads for single-source drugs to be 10%-20% below AWP<sup>123</sup> (which is within my liability threshold of expectations developed below). The spreads for "off-patent" (multi-source) drugs ranged from 60-85% below AWP.
  - Based on the OIG Report for December 1997, spreads average 18.5% off AWP for 10 single-source physician-administered drugs in 1995 and the spreads for 9 multi-source physician-administered drugs ranged from 41.6-90% off AWP. For

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<sup>120</sup> Sixteen of the 36 studies addressed a variety of Medicare Part B drugs, other than albuterol.

<sup>121</sup> For the full citations of these and other studies referenced in this section, see Attachment D to this Testimony.

<sup>122</sup> I first introduced these two surveys in my September 3, 2004 Declaration in Support of Class Certification.

<sup>123</sup> A "spread off AWP" is calculated as  $(AWP - ASP)/AWP = x$ . Such as spread is related to my calculation of spread as follows:  $(AWP - ASP)/ASP = x/(1-x)$ . Hence, if  $x = 20\% = 0.20$ ;  $(AWP - ASP)/ASP = 25\% = 0.25$ .

these same drugs in 1996, spreads averaged 18.9% off AWP for single-source drugs and averaged 62% for multi-source drugs.<sup>124</sup>

- The OIG report from December 2004, “Medicare Payments to Oncologists,” calculated payment-to-cost ratios for 16 drugs. Of those 16, 13 were single-source drugs with a weighted average payment-to-cost ratio (spread) of 14% and three multi-source drugs had a weighted average ratio of 376%.
- CMS used the Federal Register (Vol. 69, No. 4, page 1085, January 7, 2004) to introduce measures of spreads on single-source and multi-source physician-administered drugs from surveys reported in OIG (2000) and GAO (2001); see Attachment D. The spreads were introduced in support of enacting the *MPDIMA*. The spreads found for single-source drugs (excluding Kytril and Anzemet) were less than 18%; for multi-source drugs (excluding dexamethesone sodium phosphate) ranged from 24% to 84%; and on average the spreads were 16% for single-source drugs and 54% for multi-source drugs.
- Based upon these studies, I conclude that the publicly available survey evidence generally informing the government, policy makers, and industry participants about spreads **on single-source physician-administered drugs** over much of the Damage Period suggested that the spreads were not excessive.

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<sup>124</sup> The range of percentage savings reported was 15%-29% in 1995 for 10 of 11 single source drugs (excluding Novantrone), which under simple assumptions are equivalent to spreads off AWP and comparable to the spreads that I find generally for single source drugs. The OIG reported percentage savings for one single-source drug in 1995, Mitoxantrone Hydrochloride, J9293 (Novantrone), to be 52%; however, this seems to be an anomaly, since it drops to 19% in 1996. The range of percentage savings for the 11 single-source drugs in 1996 was 13% to 30%; the range for multi-source drugs was 44%-92%.

d) A variety of surveys purported to address **multi-source physician-administered drugs focus exclusively upon the drug albuterol** and its spreads, finding them to be quite large beginning in 1996 and growing considerably over time. I identify those citations in Attachment D. The reports focusing upon albuterol account **for approximately 22% of those cited**. Hence, these large spreads that began to reach public awareness in 1996, were for **a single generic physician-administered drug**, which is obviously of interest to Schering- Plough. The observation that **the spreads for a single drug were large would certainly not provide sufficient evidence** to the government, policy makers, and industry participants **that all spreads on all physician-administered drugs were large**. Indeed, the results of the OIG and ASCO surveys and analyses upon which I relied and which looked at a broader cross section of drugs at later points in time, found just the opposite.

e) Medicare would not alter their reimbursement practices based upon a single generic Part B drug or on several multi-source self-administered generic drugs first reported in 1996. Hence, the evidence that the spread on albuterol was large in 1996 and became larger by 2000 (whether calculated relative to AWP or ASP) was not sufficient to make it cost effective for public and private-sector payors to alter their entire claims reimbursement practices for physician-administered drugs generally.<sup>125</sup>

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<sup>125</sup> While payors understood that the relationship between AWP and provider acquisition costs was changing by the end of the 1990s, they continued to use AWP as the basis for reimbursement, as recognized by the Court, Defendants' Expert Mr. Young and Dr. Berndt.

- As the Court states at p. 7 of the *Memorandum and Order*, "Throughout the class period, from 1991 to the present, AWP has been the pricing benchmark for most pharmaceutical sales in the United States. (Hartman Decl. attach. D ¶¶ 29-30; Schondelmeyer ¶ 36.) It is akin to a sticker price for automobiles, setting the pricing baseline."

Likewise, the sporadic survey information that the spreads on **some** multi-source drugs were large for **some** providers over the 1990s was not sufficient to make it cost effective for payors to alter their entire claims reimbursement practices for physician administered drugs generally.

f) Medicare is a large governmental and political organization. While we are focusing on one concern of Medicare, reimbursement for physician-administered drugs, it is a small concern relative to all of the daunting issues that Medicare deals with on a continual basis. The reimbursement for Part B drugs truly falls into the category of “the importance of being unimportant,” as designated by Professor Berndt.

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- The prevalence of AWP as the basis for reimbursement decisions by payors results from its ease of implementation. From a claims administration point of view, it is simply most cost effective for a TPP to take the AWP as reported and reimburse off of that AWP.
  - In his ¶ 49 of Rebuttal Declaration, Mr. Young correctly observes “The use of AWP by commercial Health Plans as a benchmark for expressing reimbursement limitations for prescription drugs dispensed to the plans’ members expanded in the 1980’s. The expanded use corresponded with (i) the growth of private insurance coverage for prescription drugs, (ii) the increased implementation of computer programs to manage the large volume of claims relating to drugs dispensed from retail pharmacies, and (iii) the shift from indemnity type coverage (based on pharmacy or physician ‘charges’) to coverage based on negotiated reimbursement rates (discussed in detail below). **The published benchmark provided a standardized and programmable means of implementing claims processing systems that could handle the wide-ranging discounts negotiated with individual pharmacies for millions of retail pharmacy claims.**”
  - It has proved quite difficult and costly for payors to monitor and distinguish whether alternative AWPs have become inappropriate signals for provider acquisition cost. As a result, payors have been slow to attempt to address and correct suspicions regarding growing spreads. As stated by Dr. Berndt in his February 9, 2005 Report at ¶ 191, “When medical benefit expenditure data are poorly monitored and ‘tracking patient data is nearly impossible’, and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit.”
  - Dr. Berndt has also identified a plausible explanation for why payors have not aggressively identified and eliminated fraudulently excessive overcharges on physician-administered drugs – the importance of being unimportant. While he has introduced this concept to explain payors’ neglect generally in monitoring and attempting to control the claims for reimbursement for of **all** drugs, this concept is **even more relevant** to physician-administered drugs, which account for a small percentage of all drug expenditures. Until recently it has been simply too costly for TPPs to monitor closely enough reimbursement of all drugs generally and physician-administered specifically to defeat the fraud alleged in this matter.

g) It is analytically unfounded and self-serving to leap from survey information regarding spreads **on self-administered generic Medicaid drugs and selected generic physician-administered drugs** to all physician-administered drugs reimbursed under Medicare Part B. While hindsight, illuminated through discovery in this litigation and other related litigation, demonstrates that the substantial spreads found with generic self-administered drugs and selected generic physician-administered drugs in the latter half of the 1990s were indeed reflected in spreads for physician-administered drugs generally, such a general understanding simply did not exist at that time. No consistent body of survey information supported such a *systematic* understanding, let alone such an understanding with respect to each of Defendants' suspect drugs and the scheme's associated with them. Anecdotal information for some individual Part B drugs was not sufficient to change the overall expectation throughout the 1990s that the AWP provided *a reasonable expectation* for the EAC of Part B drugs. Indeed, it is impossible to explain why Medicare, if as well informed as posited by Defendants, would have allowed itself to be economically injured to the extent it was in the Lupron and Zoladex matters<sup>126</sup> and in the case of Vincasar.<sup>127</sup>

h) Reflection on the attributes of an efficient and economically-rational reimbursement system suggests that Medicare **would not want to respond in an incremental fashion** to specific news about increased spreads for some specific set of physician-

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<sup>126</sup> See *United States of America v. TAP Pharmaceutical Products, Inc., Sentencing Memorandum of the United States*, United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY (hereafter, *Lupron Sentencing Memorandum*). See also ¶¶ 23-24.

<sup>127</sup> See ¶ 22.

administered drugs. Medicare's policy under Part B has been to implement cost-based reimbursement which reflects the relative values and costs of physician services (see the discussion of Medicare's RBRVS system in ¶ 13 above) and the relative costs of drugs (see Attachment C). Under this policy, the amounts allowed for alternative physician-administered drug therapies have been related to Medicare's understanding of their costs (i.e., their AWPs) by some fixed and common percentage. If Medicare were to respond immediately to "new information" about inflated spreads for one or a small set of drugs, that response would come at large administrative costs. For example, CMS could have decided to decrease the payment for Part B physician-administered drugs overall by decreasing the portion of AWP paid (say by decreasing it from 95% to 85%). However, this strategy would have led to unintended decreases in the payments for other drugs not subject to a manufacturer scheme to elevate spreads. If, instead, CMS implemented a payment policy for the physician-administered drugs at issue here that was separate from other physician-administered drugs, two new reimbursement systems would need to have been developed and put into place. Either of these policy choices would have been quite costly to CMS, explaining why information on excessive spreads would have to be "egregious and systematic" before it would make sense for a large agency to reform its basic payment practices.

- i) Likewise, there were isolated attempts to inform HCFA and Medicare of the AWP inflation scheme. For example, a letter from Ven-A-Care to Dr. Bruce Vladeck of

HCFA dated October 2, 1996 alerted HCFA as follows:<sup>128</sup>

- “AWP has become the benchmark in the industry for establishing pharmaceutical reimbursement. ... Unfortunately, the pharmaceutical manufacturers have circumvented the intent of the government’s reimbursement methodology by falsely reporting inflated AWP pricing information enabling providers to reap windfall profits from the provision of infusion and respiratory drugs.” (at p. 3)
  - “The manufacturers are and have been reporting false and fraudulent drug pricing information, including a drug’s AWP, direct price, “DP”, and wholesaler acquisition cost, “WAC” ... By falsely inflating drug pricing information, the drug manufacturers increase the profit margins enjoyed by their customers, thereby driving demand upward and increasing utilization.” (at p. 4)
  - “Seizing the opportunity to exploit their control over drug prices, the drug manufacturers have in some instances, reported higher prices for generic products than the equivalent brand.” (at p. 4)
  - “The drug manufacturers are further exploiting their ability to falsify pricing information by using their falsifications of AWP as a marketing tool. ... Our company has been solicited on numerous occasions by drug manufacturers who brag about their use of falsely inflated pricing information as a reason for purchasing their product over a competitor’s with a lower AWP.” (at p. 5)
  - “We understand that the HCFA may be examining a plan that would, for Medicare only, abandon the AWP reimbursement methodology. ... this approach is based on the erroneous assumption that there is something wrong with the historical concept of AWP. The damage to the Medicare and Medicaid programs is being caused by false pricing information being submitted by the drug manufacturers rather than truthful representations of AWP. ... any plan must insure that there is truth and honesty in drug pricing information provided by the manufacturers and upon which reimbursement decisions are based.” (at p. 5)
- j) Reliance on such discovery materials as demonstration that HCFA and Medicare were not deceived by the alleged AWP inflation scheme misses the point. The fact is

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<sup>128</sup> Letter from Z. Bently, Ven-A-Care to Dr. Bruce Vladeck, HCFA, dated October 2, 1996 in re Excessive Reimbursements for Certain Pharmaceuticals by the Medicare and Medicaid Programs. Also marked as Exhibit 34 to my deposition in this matter, February 27, 2006 and Exhibit L to Steven Edwards Declaration filed with the *BMS Motion for Summary Judgment*, March 15, 2006.

that institutional knowledge is slow to be disseminated, institutionally assimilated and, for good reason (as discussed in ¶ 77.h) above), slow to be acted upon. In the mid to late 1990s, HCFA, CMS and Medicare carriers were becoming aware of **instances** where “the drug manufacturers are further exploiting their ability to falsify pricing information by using their falsifications of AWP as a marketing tool.” (as cited in ¶ 77.i), immediately above). Over the same period, HCFA and CMS were becoming aware of **instances** of large, indeed sometimes substantially large, spreads for multi-source physician-administered drugs. However, the evidence that I find publicly available to inform HCFA, CMS and Medicare carriers regarding how far AWP had come to deviate from the reliable cost-based signal that it had been through the 1980s are sporadic, idiosyncratic, and *certainly not systematic*. The evidence certainly was not overwhelmingly sufficient to support restructuring Medicare’s reimbursement practices and procedures. It was the slowness of Medicare and HCFA to fully understand the existence and the extent of the existence of the AWP inflation scheme, to understand the economic injury induced by the scheme and to act upon that understanding, which was exploited by Defendants through the AWP inflation scheme.

78. However, CMS, Medicare and Medicaid did continue to evaluate pricing information for a growing number of drugs revealing increasingly large spreads, leading to a growing awareness of the injury to payors systematically induced by AWP-based reimbursement procedures. By 2003, CMS was able to finally statutorily formalize the growing awareness of the abuse of AWP-based reimbursement through the 2003 *MPDIMA* for physician-administered drugs. Note that while CMS thereby returned Medicare reimbursement to a cost-based system in

2003, it allowed for institutional inertia by moving to 85% of AWP in the transition year (2004) and finally to ASP in 2005. The *OIG Compliance Program Guidance* put in place analogous practices and procedures for reimbursement of self-administered drugs in May 2003. Note that in both cases, manufacturers are now required to provide sufficient information for consumers and payors to understand the acquisition cost for which AWP has been the list price.<sup>129</sup>

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<sup>129</sup> For example, according to the *OIG Compliance Program Guidance* at pages 23733-37:

“Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. ...”

Where appropriate, manufacturers’ reported prices [therefore] should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products. ... Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. ...”

The ‘spread’ is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the ‘spread’, it controls its customer’s profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at ’95 percent of average wholesale price.’ ... Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller’s immediate customers from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the ‘spread’ to induce customers to purchase its product.”

79. According to Defendants' theory of competitive markets, this slowly-accumulating information, revealed incrementally over time through these sources (surveys, the public press and inside whistle-blowers) should have been immediately and systematically incorporated into Medicare's, Medicare carriers' and TPP's reimbursement practices and procedures in a fashion not unlike the immediate incorporation of information by the stock market. Any applied economist, focusing upon the practices and procedures of institutions in markets understands that application of the neoclassical competitive paradigm in that way is naïve. This is certainly true for the markets at issue here.

80. Indeed, one of Defendants' experts, Dr. Daniel McFadden has summarized<sup>130</sup> a body of applied and experimental research explaining why market participants are slow to assimilate and act upon information summarizing possible market changes under conditions of uncertainty and non-transparency. While his discussion focuses upon individuals making decisions in the health care services delivery market, the conclusions are equally appropriate to institutions.<sup>131</sup> For example, McFadden identifies the following:<sup>132</sup>

- a) “[C]onsumers show a reluctance to trade away from any position in which they are established,” preferring the current market position and viewing “changes with

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<sup>130</sup> See Daniel McFadden, “Free Markets and Fettered Consumers,” *American Economic Review*, 2006, 96(1), pp. 5-29.

<sup>131</sup> For examples of management science research into such institutional inertia see G. Szulanski, (1996), “Exploring internal stickiness: Impediments to the transfer of best practice within the firm,” *Strategic Management Journal*, 17, pp. 27-43; and M.T. Hansen, (1999), “The search-transfer problem: The role of weak ties in sharing knowledge across organization subunits,” *Administrative Science Quarterly*, 44(1), pp. 82-111.

<sup>132</sup> At pages 12-13; 16, 16, 16, and 12-13 respectively.

- distaste.” Some researchers in this area of rational consumer choice refer to the current market position as the status quo.<sup>133</sup>
- b) Institutions monitoring market changes and considering changing operational practices and procedures face costs of adjustment and the risk of being the first-mover, particularly when it requires negotiating terms that no other firm is seeking.<sup>134</sup> “The classical idea of herd mentality is that social animals find it easier and more comfortable to adhere to a group, accept group roles, and mimic group behavior than to act independently.”
- c) “...(O)ur primary source of information on new objects comes from others, through observation, advice, and association. McFadden and Kenneth E. Train (1996) show that in innovation games with uncertain payoff, it may pay to wait, and learn by observing rather than learn by doing.”
- d) “Charles F. Manski (1991) has explored the possibility that individuals faced with dynamic stochastic decision problems that pose immense computational challenges may simply look to others to infer valuation function to be used to judge the future payoffs of current acts...”
- e) The observation that “Consumers show a reluctance to trade away from any position in which they are established,” preferring their current state and viewing “change

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<sup>133</sup> The importance of “status quo bias” in preventing consumers from switching to alternative options that would make them better off has been demonstrated by R. Hartman, M. Doane and C.K. Woo (1991), “Consumer Rationality and the Status Quo,” *Quarterly Journal of Economics*, Vol. 106, No. 1, pp. 141-162.

<sup>134</sup> Not only do institutions wait to confirm their changing understanding of the shifting competitive terrain, they delay commitment of the economic resources required to accommodate that shifting economic terrain until they are confident of the changes. Without a critical mass of participants, and huge capital expenditures, it would be impossible for any single Plaintiff or Class member to effect any changes on the industry as a whole in order to counteract the AWP scheme.

with distaste,” is demonstrated compellingly by the deposition testimony of Edward Lemke, Director of Fee Schedule Management for the TPP, Humana Insurance.

“Q: If in fact an alternative benchmark did exist, we can agree that Humana would be free to start using that in its contracts, correct?  
A: Not necessarily.  
Q: Why not?  
A: Provider knowledge.  
Q: What do you mean by that?  
A: In negotiating with providers, they are familiar with Medicare, where it is, what it is. Been with them long enough that they have full knowledge of it and understanding and feel comfortable with it, as well as on the drug side, they are well aware of and had experience with and, quote, unquote have faith in AWP. If we were to introduce wholesale acquisition costs as part of our negotiation with a provider, there will be all kind [sic] of red flags that would go up and say we don’t know what that is and we don’t want any part of it.”<sup>135</sup>

81. I conclude that while sporadic information on increasing spreads for some drugs was incrementally gaining attention by varying entities through varying sources, the principal determiners of reimbursement rates for physician administered drugs, Medicare and Medicare carriers, acted upon this information as institutions and individuals generally do in a variety of similarly complex markets. They revealed status quo bias, slowly realizing the import of the accumulating information until that point was reached where institutionally they acted and revamped their reimbursement procedures to again return reimbursement to the cost-based

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<sup>135</sup> Deposition of Edward Lemke, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, January 12, 2005, pp. 100-101. Joe Spahn’s (Senior Health Care Consultant for Anthem, Blue Cross/Blue Shield for Anthem Midwest Region) deposition testimony indicates that private TPPs therefore rely upon Medicare’s practices and procedures:

“A. Well, my understanding from the meetings I’ve had with provider relations folks, it seems to be that physicians talk in terms of Medicare’s the benchmark and, you know, they intend to compare what everyone pays to what Medicare pays. ...  
Q. ... do you know whether or not providers insist on the Medicare amount as a baseline amount?  
A. Again, going from feedback that I’m getting when I’m in these meetings, I would say that they usually would want – in general, it seems like that’s kind of the baseline.” (pp.76-77)

system Medicare was believed to be. This “slow” response is actually economically rational from the point of view of CMS, as I have explained above. It is corroborated by Dr. Berndt’s insights into the “Importance of Being Unimportant,” which I develop more fully below for the TPPs in Class 3. Certainly the behavior of CMS, Medicare and Medicare carriers provide compelling evidence *from a natural experiment of observing large institutions*, limited by bureaucratic practices and procedures, responding under uncertainty to complex information and noisy signals. Those institutions move slowly. This has been my position throughout my testimony to this Court.

82. Taking this analysis as my current point of departure, I now turn to Class 3. I analyze liability and damages, taking account of what the members of Class 3 knew.

## **VI. ANALYSIS OF CLASS 3 INJURY AND DAMAGES**

### **A. Overview – What is the Injury to Class 3?**

83. While the members of Class 3 include Massachusetts TPPs and consumers paying for physician-administered drugs outside of Medicare, it is useful to identify those Class members that are most important in determining causation, injury and damages. They are the third-party payors (TPPs) in Class 3, since the TPPs generally negotiate the contracts with the providers. For the most part, the consumers in Class 3 pay coinsurance amounts related to these reimbursement rates. Only a small percentage of Class 3 members are self-payors; these Class members have no power to negotiate with providers for reimbursement rates.

84. I am advised that this Court may conclude that the rights of claims of TPP members in Class 3 may not be adjudicated in accordance with the same “plain meaning”

interpretation of AWP as may be the rights of claims under Class 2. As a result, the following questions arise: Were the TPP members of Class 3 (and their insureds) impacted and injured by the AWP Inflation Scheme? How and to what degree were they injured?

85. Certainly, if the costs of physician-administered drugs to members of Class 3 were higher on a class-wide basis than they would have been absent the AWP Inflation Scheme, those Class members were injured and damaged. This injury and overcharge damage would have occurred whether the Class member knew it or not. This injury and overcharge damage would have occurred if the Class member had no expectations about the relationship between the basis for its reimbursement (AWP) and the provider acquisition cost being reimbursed.<sup>136</sup> Not unlike a price fixing conspiracy, ignorance of the conspiracy (or in this case, the AWP Inflation Scheme) does not in any way insulate Class members from the injury.

86. What about those TPPs in Class 3 that were more sophisticated; that did attempt to gather market information and refine their knowledge and expectations; that were motivated to enter into negotiations with providers with the thought of aggressively striking a “good bargain”? Were they injured and to what degree?

87. In answering this question it is important to understand the violation and the world, but-for the violation. In any antitrust case, if anti-competitive behavior has harmed a class of individuals, the measure of damages is usually the amount to which the class members were affected relative to the but-for competitive market result.

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<sup>136</sup> Such a class member would likely agree in negotiations with providers to pay some basic set of reimbursement rates with little thought to the opportunity to aggressively negotiate those rates.

88. In this case, we have an alleged fraud, which as discussed in Section III, put the TPP Class members in a disadvantageous position as they negotiated bargaining equilibria with providers. TPP members of Class 3 were simply unable to strike a “good bargain.”

89. What would they need to know to strike a good bargain? Clearly, to strike a bargain where each side of the negotiation had the same information, the TPPs would need to know the spreads for all relevant NDCs. With equal, rather than asymmetric knowledge and information, both sides would then negotiate on a level informational playing field. If the TPPs knew as much as manufacturers and providers (i.e., what the *OIG Compliance Program Guidance* and *MPDIMA* now requires), they would know the ASPs by NDCs. They could then try to negotiate reimbursement rates to providers to  $ASP + \epsilon$  (a small amount), by NDC.

90. The TPPs certainly did not know the spreads by NDCs. To do so, they would have been required to do the following:

- Detect and assimilate all *OIG/MPDIMA*-type information by NDC and J-Code.
- Differentiate, in their data processing and information management systems, discounts off AWPs by NDC and/or J-Code.
- Negotiate with providers at the NDC level for all relevant drugs.

These requirements are impossible. Indeed, the market understands that these requirements are impossible. Even if possible to gather such information, it would be cost prohibitive to do so. To introduce and continue to refine this much information in the data processing systems of the TPPs would be cost prohibitive. To negotiate with each provider to this level of detail would

require months of negotiation, which would be cost prohibitive. It is this impossibility and this cost-prohibitiveness that has been exploited by Defendants.

91. This market requires and relies upon simple rules of thumb regarding overall discounts off AWP for Classes of drugs, much like the resource-based relative-value scales (RBRVS) Medicare uses to make decisions regarding reimbursements to physician-service providers. As FDB says (see ¶ 15 above): “AWP was developed to provide a price, *which all parties could agree upon*” (emphasis added). The entities of this market can agree upon AWP, whether they know what it means or not. As a matter of economics, the question arises what is the average percentage off AWP that TPPs could have come to understand accurately reflected the acquisition costs of the providers (their ASPs) plus “some margin.” The Court, Mr. Young and the TPPs themselves<sup>137</sup> admit that TPPs reimburse at AWP minus x%, where x% = (13%-18%) for single-source self-administered drugs. More importantly, Mr. Young and the TPPs admit that such reimbursement covers provider (pharmacy) acquisition costs (RAC ≈ WAC) and allows some profit to the providers (pharmacies).

92. What have Class 3 TPPs come to understand x% is and should be, so that physicians can cover their costs and perhaps earn a “reasonable margin” rather than “egregious profit” on the drugs they administer? This would be the rule of thumb that they would use when bargaining with providers. If manufacturers then secretly increased spreads such that reimbursement rates negotiated by TPPs with the expectation of an average spread of x% led in reality to “egregious” overcharges and profits unbeknownst to TPPs, by a rule of reason approach, it would seem that those secret spreads constitute fraud injuring the Class members.

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<sup>137</sup> See the *Memorandum and Order*, at p. 63: “Hartman estimates that the range of actual reimbursement rates in TPP contracts with providers in the self-administered context was AWP minus 13% to 17% (Hartman Decl. ¶ 30(g)); Young uses the range of AWP minus 14% to 18% (Young ¶ 134).” See also ¶¶ 111-112 below.

93. In this Section, I characterize what shaped TPPs expectations. I analyze the range of the discounts x% off AWP that Class 3 TPPs generally believed and expected to allow for a reimbursement rate that, *on average*, covered provider drug costs while offering “some reasonable profit margin” to physicians. I examine whether Class 3 TPPs were, or could be, sufficiently adept to uncover information of systematic deviations in pricing practices by manufacturers such that the TPPs expected spread of x% was no longer a basis for “reasonable” reimbursement.

94. I conclude that **there was a range of values of x%** which TPPs believed characterized reimbursement rates that were sufficient to cover the cost of physician-administered drugs while offering a “reasonable” margin or profit to the provider administering those drugs. I conclude that TPPs were insufficiently positioned to uncover the systematic information required to better refine and improve their expectations to **renegotiate x%** and thereby mitigate the overcharges induced by the AWP Inflation Scheme. More importantly I conclude that TPPs were insufficiently positioned to make use of such information, even if they had it, to **renegotiate x%** and thereby mitigate the overcharges induced by the AWP Inflation Scheme.

95. Once I quantify the range of those expectations (which I present in Section VII), I set a threshold spread for causation and liability, which I call my Yardstick Spread (which I also do in Section VII). This Yardstick Threshold Spread is **greater than the range of expectations** I find, thereby making that threshold spread conservative as a measure of fraudulent exploitation of TPPs’ range of expectations regarding systematic spreads on physician-administered drugs.

## B. Ten Reasons Why the AWP Inflation Scheme Was Successful

96. I understand that Defendants contend that the TPP members of Class 3 are agile and mobile sophisticated economic entities, able to monitor and gather all available information in the market, process it and use it efficiently and regularly to refine their expectations to accurately measure in real time the “spreads” or “Return to Practice” **for each drug being reimbursed.** The analogy I used above is stock brokers or day traders, who incorporate all market information, instantaneously, **by company** in order to accurately measure prices at which the equity of those companies should be bought and sold.

Given the substantial complexity of the systems for submitting, monitoring and translating information into amounts allowed for reimbursement for thousands of physician-administered pharmaceuticals and the manner by which that information is made available to TPPs, I find Defendants’ characterization wholly inaccurate. As Dr. Anderson, Professor of Medicine and Health Policy at Johns Hopkins, testified in *Lupron*, with 65,000 drugs “negotiation of a specific price for each . . . would be administratively impossible,”<sup>138</sup> thus fostering the AWP pricing standard. If TPPs were informed, could negotiate and implement alternative reimbursement rates by drug, they would not negotiate rates **at some common discount off AWP.** A different discount would be determined for each of thousands of drugs, in order to account for different spreads revealed for each. As mentioned above, such a system would be unworkable within the current information management systems, practices and procedures in this industry.

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<sup>138</sup> Declaration of Gerrard F. Andersen in Support of Plaintiffs’ Motion for Class Certification in *In re Lupron Marketing and Sales Practice Litigation*, MDL No. 1430.

97. I now present ten real-world features of private TPP reimbursement for physician-administered pharmaceuticals and discuss their implications for injury and damages to members of Class 3.

**1. *Private TPPs with No Explicit Spread Expectations are Nevertheless Impacted and Injured***

98. It would seem that Defendants believe that TPPs holding little or no expectations about spreads on physician-administered drugs are uninjured by the AWP Inflation Scheme. That argument makes little sense; it is analogous to arguing that if someone picks my pocket and I neither expected nor realized it, I was not injured. Such a TPP likely would enter negotiations with providers and offer to pay “what the normal reimbursement rates were” or perhaps “what Medicare reimbursed,” a position apparently found naïve by Defendants and not a basis for injury or recovery. Like Blanche Dubois in “A Streetcar Named Desire,” who “always relied upon the kindness of strangers,” Defendants seem to argue that such a TPP cannot recover for its inattentiveness to its own injury.

99. However, two Nobel Laureates in Economics concur with Tennessee Williams. Specifically, in quoting Kenneth Arrow, Daniel McFadden observes “every commercial transaction involves an element of trust.”<sup>139</sup> The TPPs in this category entered into negotiations with “an element of trust.” They did not negotiate or shop aggressively, perhaps trusting or assuming that “competition” somewhere was protecting them. I doubt these TPPs would explicitly suggest to providers that they “charge as much as they could, and if possible maybe even fraudulently charge some more.”

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<sup>139</sup> Daniel McFadden, “Free Markets and Fettered Consumers,” *op. cit.*, p. 9.

100. In any case, these TPPs were as vulnerable, if not **more vulnerable**, to impact and injury from the fraud than were those TPPs with expectations that proved to be wrong. These TPPs were overcharged and damaged.

## **2. Private TPPs Relied upon Medicare Reimbursement Practices and Procedure**

101. For those TPPs that did have expectations, which they tried to inform and refine – what information sources and behavior could they look to? According to the 2003 *MedPAC Report*, Medicare has been a principle source of expectations about reimbursement practices, hence, underlying spreads:

“Until recently, private payers devoted little attention to price and utilization of specialty [i.e., physician-administered] drugs. Their payment systems, and **the problems associated with them**, have mirrored Medicare’s AWP-based formula. These drugs are most often administered through a health plan’s major medical benefit rather than as part of the pharmacy benefit. When billing drugs through the major medical benefit, physicians purchase needed drugs and submit claims to their patient’s insurance plan along with other claims for services. **Any discounts or rebates that the physicians receive for drug purchases are not passed on to the plan**” (emphasis added).<sup>140</sup>

102. This quote corroborates other evidence I have found in the record.<sup>141</sup> Based upon this characterization in the *MedPAC Report* and other evidence, I conclude the following about reimbursement practices of private TPPs:

- a) TPPs generally expected that Medicare AWP-based reimbursement rates were cost-based historically. There was no watershed event suggesting this was not the case until the 2003 enactment of the *MPDIMA*. And even with the passage of the

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<sup>140</sup> *MedPAC Report*, Chapter 9, p. 166.

<sup>141</sup> See, for example, footnote 166.

*MPDIMA*, inertia and status quo bias has characterized immediate TPP responses to what was, in reality, a new reimbursement paradigm.<sup>142</sup>

- b) Over the Class Period, Medicare's reimbursement rates moved from 100% of AWP to 95% of AWP (in 1998) to 85% of AWP (in 2004). Hence, over the entire Class Period, private TPPs saw the major insurer in the country (Medicare) reimburse for physician-administered drugs at AWP minus (0%-15%), reimbursement rates with discounts generally less aggressive than those negotiated for single-source self-administered drugs, which this Court has recognized as being AWP minus 13%-18%. Hence, Medicare's reimbursement practices and procedures for physician-administered drugs certainly must have signaled private TPPs that reimbursement at AWP – (0%-15%) was not providing “mega-spreads” or “egregious profits” to providers.
- c) Indeed, it is most likely that since Medicare was the major insurer in the market, the observations by Dr. McFadden of “herd mentality” and the fact “that individuals faced with dynamic … decision problems … may simply look to others to … judge the future payoffs of future acts (see Section V above)” are more likely appropriate to private TPPs in Class 3 than to Medicare and Medicare regional carriers, since Medicare is viewed as setting the standard for these reimbursement practices. Furthermore, since the many OIG/GAO reports aimed at measuring spreads for Medicare (Part B) and Medicaid are aimed at CMS<sup>143</sup>

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<sup>142</sup> This was certainly the immediate response of BCBS/MA's; see ¶ 118.d) below.

<sup>143</sup> See, for examples, OIG, Excessive Medicare Payment for Prescriptive Drugs (OEI-03-97-00290), December 1997, Appendix D and OIG, Medicare Reimbursement of Prescriptive Drugs (OEI-03-00-00310), January 2001, Appendix F.

specifically and calculate savings that could be realized by the federal government with changes in the reimbursement formulas, it is certainly more likely that CMS would review and act upon the information contained in them than would private TPPs, everything else equal.<sup>144</sup>

103. While a sufficiently comprehensive survey of TPPs knowledge, understanding and expectations over the Class Period would likely be unreliable for reasons of survey design and response biases, observation of the result of a significant natural experiment is available. Specifically, Medicare, Medicare carriers, HCFA and CMS did receive the information put forward by OIG and GAO over the Class Period, and they were institutionally responsible to make Medicare reimbursement cost-based, for reasons discussed above (¶¶ 9-14 above). In light of that mandate and in light of the fact that CMS was the entity which the OIG and GAO reports were designed to inform, I find that CMS did not move to make reimbursement cost based **until 2003** (through the *OIG Compliance Program Guidance* and the *MPDIMA*). Given that slow response, and given the fact that institutions generally display “herd mentality,” status quo bias, and “look to others” when making difficult decisions, it is not surprising that private TPPs were

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<sup>144</sup> It is also important to note, that for the first part of the Class Period, access to many of these documents was not as easily accessible as they are today, in large part due to the limited internet access. Although the first trials of the World Wide Web appeared in December 1990, the Web remained out of the general public’s eye for several years. In the early 1990’s the Web was used primarily as an academic resource. There were only about 26 sites by the end of 1992 (“History of the World Wide Web” as accessed <http://www.nethistory.info>). Before Netscape, “the Internet did not exist for most people” (Kelly, Kevin, “We Are the Web” *Wired* Vol. 13, No. 8, August 1995). With the introduction of the Netscape browser in 1995, the general public had access to a user-friendly approach to the Web. During a period in 1995 and 1996, Internet traffic doubled every three to four months (Odlyzko, Andrew, “Internet growth: Myth and reality, use and abuse”, *Journal of Computer Resource Management*, p. 23-27, 2001). The popular usage of search engines further opened up the Web in the mid 1990s (“History of the World Wide Web”, *op. cit.*). As the nascent Web became more familiar, the public’s perception of it evolved. A 1996 article in *Wired* magazine exemplified this saying, “A year and a half ago, the content of the Web was heavily tilted toward a few niches: there was a lot about Unix and UFOs, not much about real estate or poetry” (Steinberg, Steve, “Seek and Ye Shall Find (Maybe)”, *Wired*, Vol. 4, No. 5, p. 108, May 1996).

unable to inform themselves sufficiently to reasonably improve their expectations and to improve their bargaining with parties (providers) that had asymmetrically better information.

### **3. Market-Wide Price Compendia Purposefully Misled Expectations**

104. The source of much TPP information concerning list prices and the expectations that could reasonably be derived from list prices were the providers of electronically integratable drug price information, such as First DataBank (FDB) and Medispan. As mentioned above (¶ 15), FDB and Medispan dominated this market for much of the 1990s through the present. For much of that period, FDB was the dominant of the two.

As also noted above, in promoting their AWP and WAC price data, FDB asserted that their AWP “is the average wholesale price. That is, AWP is the [weighted] average of the prices charged by the national drug wholesalers for a given product (NDC).” There was no easy way for TPPs to uncover the deception in this claim.

105. Those TPPs purchasing FDB data for claims processing, **which included most TPPs** using electronic claims processing (which were most TPPs by claims volume), in many cases selected the FDB data precisely because they believed that the AWP did reflect a surveyed weighted-average wholesale price, i.e., *the weighted average price of drugs sold to providers at wholesale*. The remaining source of AWP information, Red Book,<sup>145</sup> made the same implicit

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<sup>145</sup> Red Book provided electronic list price information; however, this data base was not electronically integrateable and not felt to be competitive with the others by the FTC; see footnote 13 above. However, in their published books, Red Book also inferred that their prices were averages. For example from the *1991 Drug Topics Red Book*: “The actual price paid by retailers, however, may fall above or below those reported prices ... Pricing information is based on data obtained from manufacturers, distributors, and other suppliers ... The publisher of Red Book has exercised the greatest care and caution in compiling prices” (p. 85).

claim. Some Defendant's discovery documents suggest they believed the claims made by FDB.<sup>146</sup>

106. Such a claim would certainly provide a basis for what were believed to be **reasonable spread expectations**. Indeed, TPPs believing these FDB claims would expect that **AWP + (10-15%)** would reflect reimbursement allowing providers to cover the acquisition cost of the drugs "plus some margin."

#### **4. *The Relative "Unimportance" of Physician-Administered Drugs***

107. As introduced and developed by Dr. Berndt in his Independent Report to this Court, the "Importance of Being Unimportant" helps describe the limited response by managed care organizations to the increase in the costs of all pharmaceuticals, self-administered and physician-administered. Specifically, Dr. Berndt measures and discusses the extent to which pharmaceutical reimbursements have increased substantially since 1994. The first factor he identifies as a reason is "the importance of being unimportant," meaning that despite their significance on an absolute dollar basis, drug reimbursements still accounted for only 5-8% of all health care expenditures. According to Dr. Berndt (p. 102),<sup>147</sup> citing Alfred Marshall, "if spending on some good or service is perceived to be only a small portion of total costs, that good or service will not be as likely to be on cost cutters' radar screens; instead, they will tend to focus more on big-ticket items." As a result, he infers that managed care organizations and payors likely focused their cost cutting efforts and analyses on hospital care, physician services and "all

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<sup>146</sup> A Johnson & Johnson email from Diane Ortiz Re: AWP Reporting Issue: An Overview, September 20, 2002, Plaintiffs' Exhibit 327 (MDL-CEN00103688-90) in reaction to the change to the WAC markup by FDB states: "There was not much detail provided regarding survey techniques. J&J trade relations believe the major wholesalers are surveyed and two out of the three majors would be enough to change the price point."

<sup>147</sup> See Ernst R. Berndt, "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs*, 20(2), 2001, p. 102.

other” categories of reimbursement and expenditure. The lack of focus upon pharmaceutical reimbursement made the increased spreads induced by the fraud alleged in this matter easier to conceal and to be overlooked by all payors.

108. Prescription and administration of a particular physician-administered drug is aptly characterized as “high touch” by Dr. Berndt (at his p. 55), which I take to mean “specialized to the case at hand.” Choice of the appropriate drug is not something commonly subjected to formulary review. As a result, there is little payor oversight; critical review of a provider’s choice of drug therapy and the price of the selected drug is most typically believed to be beyond the expertise of the TPP. The provider determines the drug being administered. The choice of drug is determined by the training of the provider and the provider’s specific knowledge of the patient, the patient’s clinical profile and the patient’s medical needs.

109. Not only do TPPs feel medically inadequate to review physician/provider choice of therapy, TPPs correctly believe that such review is not cost-effective. Returning to Dr. Berndt’s insight about the importance of being unimportant, while pharmaceutical reimbursements overall have been relatively less important, **this unimportance is even more important for physician-administered drugs**, which represent a small portion of an already small component of costs (i.e., the cost of **all** pharmaceuticals).<sup>148</sup> In light of this situation, TPPs would have looked for easily ascertainable rules of thumb or signals for expectations regarding reasonable claims for reimbursement of physician-administered drugs. Since Medicare has taken the lead with such reimbursement under Part B, it is not surprising that TPPs follow Medicare’s

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<sup>148</sup> Deposition testimony confirms this insight. See, for example, Mike Beaderstadt John Deere’s Director of Provider Relations, agrees that “drug spend was a relatively small component of the overall medical benefit” (Deposition of Mike Beaderstadt, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action: 01-CV-12257-PBS, September 17, 2004, p. 68.

lead. Reliance upon AWP has followed, as has the assumption that AWP generally provides a reasonable signal for ASP.

110. TPPs have not tried harder with respect to better informing their expectations for physician-administered drug reimbursement because it would be economically irrational for them to do so. The costs would be too high (for reasons cited above) for a component of spending that is relatively small on an aggregate basis. As a result, reimbursement rates for physician-administered drugs suffered from what Dr. Berndt called “benign neglect.”<sup>149</sup>

**5. *Negotiated Reimbursement Rates for Self-Administered Drugs Shaped TPP Expectations Concerning Reasonable Spreads for Physician-Administered Drugs***

111. In footnote 137 above, I note that the Court has recognized that reimbursement rates negotiated by providers for single source drugs have fallen within the narrow range of AWP minus (13%-18%), based upon my Declarations in Support of Class Certification and Mr. Young’s Declaration in Rebuttal to Class Certification. Looking at the earlier testimony of Mr. Young, it is clear that these reimbursement rates reflected payor expectations about acquisition costs and spreads as follows.

- a) In his deposition, Mr. Young admits to the known relationship between AWP, WAC and the retail provider acquisition cost (RAC) for branded self-administered drugs:

“A: So when you say, ‘pharmacy channel,’ to say for one -- what you are referring to is for one channel within the many channels that a self-administered retail branded drug is established, in that one channel for branded retail drugs, **they generally do purchase at or around WAC** [i.e., RAC ≈ WAC], and there is generally a relatively consistent standard -- industry standard relationship between WAC and AWP. So

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<sup>149</sup> Berndt Report, ¶187. Specifically, in referring to abuses to payors, he states “With minimal vigilance [from TPPs, due to the importance of being unimportant], the possibility for unnoticed abuse and mischief is enhanced. Those able to make mischief understand the potential from benign neglect.”

within that kind of chain of qualifications, if that was the question that you were trying to get to, that would be my response.

Q: And in that specific set of circumstances that you just identified, they do correlate?

A: Because of the fact that they do buy at or around WAC and because of the fact that there is a standard industry practice to have a pretty constant relationship between the two, yes.”<sup>150</sup> (emphasis added)

- b) Mr. Young testifies that payors understood that reimbursement rates calculated as a percentage off AWP covered drug acquisition costs and a “competitive” margin to provider pharmacies.

“Payors expressed their pharmacy reimbursement **based on formulas that included a discount off of AWP** between 14% and 18% **to provide the pharmacies margin** on the drugs dispensed to their members, **understanding** that (a) pharmacies typically acquire self-administered brand name drugs at or around WAC and (b) the AWP on brand name drugs generally is stated at 20% to 25% markup over WAC (or the equivalent 16.7% or 20.0% discount off of AWP, respectively).” (emphasis added)<sup>151</sup>

- c) This admission demonstrates that payors negotiated reimbursement rates with the expectation that pharmacies would make a reasonable margin, given the pharmacies’ acquisition cost (RAC).
- d) This admission is supported by deponents cited by Mr. Young.<sup>152</sup>

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<sup>150</sup> See Young Deposition, November 18, 2004, pp. 172-173. Also, see ¶ 52 of his Rebuttal Declaration, where Mr. Young reconfirms this testimony as follows: “it is undisputed that pharmacies generally acquire brand name drugs at or around the WAC. Plaintiffs’ expert agrees that retail pharmacies normally buy branded self-administered drugs at or about WAC. Published studies have concluded that retail pharmacies generally purchase at or around WAC.” If I designate the retail acquisition cost as RAC, then RAC ≈ WAC.

<sup>151</sup> Young Rebuttal Declaration, ¶ 134.

<sup>152</sup> In footnote 75 of my December 16, 2004 Rebuttal Declaration, I cite (in more detail than provided here) the following deposition testimony from Mr. Young’s Exhibit 1m (emphasis added):

Nancy Roland of Wellmark BCBS:

“Q: At the time that you determined to reimburse Advance PCS pharmacies at rates between AWP minus 13 percent to and AWP minus 15 percent of brand name drugs, it was your understanding at that time that that reimbursement on the drugs would provide the pharmacies with **some margin above the cost that they pay for the drugs**?

A: That was my assumption.

112. These assumptions concerning reimbursements off AWP in the range of 13-18% so that providers (retail pharmacies in the case of self-administered drugs) could earn sufficient profit to stay in business certainly had some effect upon the expectations of TPPs negotiating reimbursement rates for single-source physician-administered drugs, particularly since “many of the physician-administered drugs are single-source.”<sup>153</sup> Indeed, Mr. Young explicitly suggests that under Medicare’s AWP reimbursement rates, providers earn that retailer profit cited above.<sup>154</sup>

#### **6. *The Use of J-Codes and Medical Benefit Claims Obfuscated Spreads***

113. Dr. Berndt addressed the issue of pricing non-transparency in his February 2005 Independent Report, and it has been recognized by this Court as follows:

- a) “Because physician-administered drug reimbursement has been based on a five-digit ‘J-Code’ system, which does not differentiate for strength, dosage and packaging (unlike NDCs), **the issue of pricing transparency becomes an ‘order of magnitude larger’ in this context** (Berndt ¶ 199). In summary, **when medical benefit**

John Rogers of Independent Health:

- “Q: And did Independent Health have any expectation about what the margin pharmacies would earn on their drugs would be?
- A: I don’t think we had any—any specific information ...
- A: ... We don’t want to have pharmacists go out of business”

Both deponents expected and hoped that pharmacies earned “some margin above the cost ... for the drugs [i.e., retail acquisition cost or RAC]” so that the pharmacies would not “go out of business.” Both deponents thereby indicate that reimbursement rates for branded self-administered orals (which are a strict percent off AWP) are related to drug acquisition costs with “some margin” to pharmacies to keep them in business.

<sup>153</sup> According to Dr. Berndt, “I note in passing that ... many of the physician administered drugs are single-source, and the only product in their therapeutic class” (at ¶ 103 of his February 2005 Independent Report).

<sup>154</sup> At ¶ 160 of his Rebuttal Declaration, he states “Until 1992, Medicare reimbursed physician services and drugs based on a reasonable charge methodology. Under this price-based methodology, the physicians’ entire billed charge was paid if deemed reasonable by the local Medicare carrier. That methodology resulted in physicians earning the retail margin on drugs reimbursed under Medicare.”

**expenditure data are poorly monitored and ‘tracking patient data is nearly impossible’, and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit (Berndt ¶ 191).<sup>155</sup> (emphasis added)**

- b) Dr. Berndt summarizes the conflation of these factors at ¶ 200 of his February 9, 2005 independent Report, “in the market environment for physician-administered drugs, a variety of forces – the relatively small dollar amounts they involve, the ambiguity of whether the claims stem from the medical or drug component of the health benefit, the troublesome relationships with providers who act as both buyers and sellers (and prescribers and dispensers) of physician-administered drugs, and the J-code claims system that has obfuscated the utilization and pricing of individual drug products and confounded close monitoring – have together contributed instead to a system lacking checks and balances and inviting abuse. Some of that abuse has already been uncovered in this Court and elsewhere.”

**7. *Institutional Inertia has Made Adjustments to Spread Expectations Difficult Even for Large Sophisticated TPPs***

114. The study of institutional economics or the economics of institutions and organizations has a long and diverse history and literature. The related literature finds that

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<sup>155</sup> *Memorandum and Order*, pp. 29-31. Also note, on page 42 of his February 9, 2005 Report, Dr. Berndt further describes the lack of information that has characterized payor understanding of the actual spreads during the Class Period: “In a different industry publication, an executive at AdvancePCS reports that in his experience health plans become ‘flabbergasted at what they’ve been paying for years on drugs’ on the medical side because of dramatic price markups.” (emphasis added)

Even when payors attempt to track information on drugs and the acquisition costs of drugs; even when the right to audit a PBM exists; and even when prescription drug benefit consultants are retained, there remains considerable non-transparency in the contracts, . . . billing information and accounting information. This fact is made vivid by the continued and recent attempts by payors to obtain greater pricing transparency from middlepersons and providers.

institutions are not the agile and mobile competitive entities that Defendants posit. Of the many insights provided by this branch of economics, one modest conclusion is that intra-institution interest groups making decisions in response to new and uncertain information respond slowly.

- a) Addressing organizational economics generally under the rubric, “transaction cost economics,” Oliver Williamson notes that “the core problem of the economic organization of society [is] that of facing and dealing with uncertainty.” One uncertainty that he identifies is “uncertainty [which] arises ‘from lack of communication, that is from one decision maker having no way of finding out the concurrent decisions and plans made by others.’”<sup>156</sup>
- b) Applying that notion, Bengt Holmstrom and Jean Tirole<sup>157</sup> observe that “The nature of decision-making within firms is of a different kind than individual choice in markets. … In the aggregate, firm behavior is the result of a complex joint decision process.”
- c) Summarizing these notions, Wendell Gordon<sup>158</sup> notes, “The institutions into which society is organized adjust slowly and reluctantly to assimilate and use new technical knowledge and to accommodate and adjust their own behavior norms the better to utilize this new knowledge.”

115. Even economic entities not characterized by institutional complexities and impediments to decision making have demonstrated “Status Quo Bias.”<sup>159</sup> According to the

<sup>156</sup> Oliver Williamson, “Transaction Cost Economics,” chapter 3, p. 143, quoting T. Koopmans, in R. Schmalensee and R. Willig, *Handbook of Industrial Organization*, North Holland Press, 1989.

<sup>157</sup> Bengt R. Holmstrom and Jean Tirole, *The Theory of the Firm*, chapter 2, p. 63.

<sup>158</sup> Wendell Gordon, *Institutional Economics: The Changing System*, University of Texas Press, 1990, p. 9.

<sup>159</sup> For example, see R.S. Hartman, M. J. Doane, and C.K. Woo, *op. cit.*

notion of status quo bias, economic entities become accustomed to the status quo and are reluctant to move in the face of uncertainty, **even if** such a move is economically beneficial.

116. Defendants argue that certain Class 3 TPPs, those TPPs with staff-model HMO subsidiaries, were positioned to detect, assimilate and act upon spread information. They argue that these institutions “must have known” about manufacturers’ prices, hence the large spreads. While these institutions did acquire physician-administered drugs at ASPs, such resulting ‘knowledge’ does not immediately transfer within a firm and is not automatically incorporated into their information systems or decision-making processes. There are barriers to handling anecdotal information as well as costs and impediments to systematically incorporating new information sources. There are monetary costs as well as social costs involved with utilizing information. Social costs, in this context, refer to the development of intra-firm social networks that could potentially share resources such as information and knowledge. There are monetary costs associated with identifying, documenting, codifying, warehousing, searching for, extracting and using information. TPPs are not the only firms that struggle with managing knowledge and information: “Hewlett-Packard CEO Lew Platt once said ... ‘If HP knew what HP knows, we would be three times as profitable.’”<sup>160</sup>

117. In any case, in Attachments E and F to this Direct Testimony, I formally examine purchase and reimbursement data for the largest TPP in Class 3 to which Defendants appeal, BCBS/MA. This TPP certainly must be considered “sophisticated.” It certainly possessed information concerning ASPs. If this TPP could not act upon that information, it is unlikely that others could.

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<sup>160</sup> Davenport, Thomas H., Laurence Prusak, *Working Knowledge: How Organizations Manage What They Know*, 2000, Harvard Business School Press, p. xxi.

I demonstrate in Attachments E and F that this TPP **did not apparently share information institutionally and did not act upon it**, even if the information had been shared.

118. My quantitative findings are confirmed by deposition testimony from BCBS/MA and other payors.

a) The deposition testimony of Michael T. Mulrey, **Manager of Provider Reimbursement** at BCBS/MA, provides clear indication that his expectations concerning the signaling value of AWP **were incorrect** (prior to 2003-2004) and certainly not informed by the direct purchases of BCBS/MA's staff-model HMO.

"Q. I am asking what your understanding was. Okay? Let's just start with that point. In 2000, what was your understanding of the term AWP, or average wholesale price?

A. It is the price that we would reimburse our providers, and it was the price at which we felt providers purchased their drugs at.

Q. Okay. So it is your understanding -- it was your understanding in 2000 that it was the price at which providers purchased their drugs; is that correct?

A. Yes.

Q. So, in other words, it is your position that you understood that Blue Cross/Blue Shield of Massachusetts was reimbursing providers at their average cost?

A. Yes" (pp. 87-88). ...

"Q. So in 2003-2004, as a member of the provider reimbursement group, you learned that AWP was no longer, you know, from your perspective an average of actual wholesale costs but indeed was something greater than the costs that doctors paid for drugs; right?

A. Yes" (p. 93).<sup>161</sup>

b) Mr. Mulrey's testimony clearly demonstrates BCBS/MA came to realize it had been deceived by its understanding of AWP as a measure of provider acquisition costs in 2003-2004. Following the deposition testimony cited above (at p. 112 of his deposition transcript), he states:

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<sup>161</sup> Deposition of Michael Mulrey, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL Docket No. 01-CV-12257-PBS. January 5, 2006.

“Q. Is it your position in this litigation that Blue Cross/Blue Shield of Massachusetts was misled by doctors and manufacturers through the publication of AWPs that bore little or no resemblance to actual acquisition costs at which doctors purchased drugs?

A. I mean –

Q. I am asking your position.

A. My position? It is not –...

A. -- Yes.”

- c) Mr. Mulrey’s testimony demonstrates that price and cost information **did not readily flow within this organization**, and as a result, the provider reimbursement group of BCBS/MA was unaware of specific information regarding rebate and discount policies that manufacturers offered to physician providers.
- d) Finally, Mr. Mulrey’s testimony indicates that when BCBS/MA actually became aware of the divergence of reimbursement rates from ASP **through outside information**, it remained hesitant to use that information to alter its drug reimbursement procedures from an AWP-based system until “an industry-acceptable standard” became apparent. Specifically,

“Q. When did Blue Cross/Blue Shield of Massachusetts first begin to use R.J. Health as a vendor to determine reimbursement amounts for physician-administered drugs?

A. 2005.

Q. And Blue Cross/Blue Shield of Massachusetts started using R.J. Health because Medicare no longer reimbursed for physician-administered drugs on an AWP basis; correct?

A. Yes.

Q. In the 2004 time frame before Medicare switched its reimbursement methodology, did Blue Cross/Blue Shield of Massachusetts give any consideration to revising its reimbursement methodology for physician-administered drugs?

A. Yes.

Q. What involvement, if any, did you have in that process?

A. I completed an analysis.

Q. What analysis was that?

A. An analysis of ASP pricing that Medicare was proposing against our utilization” (p. 65).

“Q. Your analysis basically involved a change in the status quo analysis? You were contemplating what would happen if Blue Cross/Blue Shield of Massachusetts switched to an ASP environment; correct?

A. "Yes" (pp. 66-67).

"Q. And as a consequence of your analysis, is it correct that Blue Cross/Blue Shield of Massachusetts elected not to shift to the ASP reimbursement methodology?

A. At this time, yes. ....

A. I mean we normally follow industry standards, and Medicare has moved to ASP. **Right now from our perspective, we don't see that as an industry-acceptable standard just yet**" (p. 72).<sup>162</sup> (emphasis added)

e) Mr. Mulrey's testimony confirms the many theories of inertial behavior by consumers and institutions put forward above. Specifically, even with internal information of ASPs,

- TPPs show a reluctance to trade away from any position in which they are established (the AWP-based reimbursement scheme)," preferring the current market position (the status quo) and viewing "change [from that status quo]<sup>163</sup>] with distaste." (McFadden, pp. 12-13)
- TPPs monitoring market changes and considering changing operational practices and procedures face costs of adjustment and the risk of being the first-mover, particularly when it requires negotiating terms that no other firm is seeking. "The classical idea of herd mentality is that social animals find it easier and more comfortable to adhere to a group, accept group roles, and mimic group behavior than to act independently." (McFadden, p. 16)
- "...(O)ur primary source of information on new objects comes from others, through observation, advice, and association. ... it may pay to wait, and learn by observing rather than learn by doing." (McFadden, p. 16)
- "... Individuals faced with dynamic ... decision problems ... may simply look to others to ... judge the future payoffs of future acts..." (McFadden, p. 16)
- Indeed, BCBS/MA's **Manager of Provider Reimbursement** learned of the large spreads and the unreliability of the reported AWP from **outside information rather than the inside information** that it gathered and could readily communicate.

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<sup>162</sup> *Ibid.*

<sup>163</sup> Hartman, Doane and Woo, *op. cit.*

- BCBS/MA was part of the herd that learned from and followed Medicare, the primary source of physician-administered drug reimbursement procedures and practices.
  - Indeed, even when the first-mover (Medicare) returned reimbursement formulas to cost-based measures (ASPs) in 2003 to begin in 2005, BCBS/MA wanted to move slowly and cautiously, first observing what the rest of the “herd” would do (“Right now from our perspective, we don't see that as an industry-acceptable standard just yet”) before committing to ASP-based reimbursement, **despite** their internal information from their staff model HMO. Status quo bias and inertia characterized BCBS/MA’s provider reimbursement group’s response to the information. As within any large institution, before a major shift occurs in operational practices, the institution wants to observe whether the newly acquired-information is indicative of a change in the economic terrain in which that institution competes.
- f) For another example, Robert C. Farias, the director of planning administration for network services and operations at Harvard Pilgrim, in his October 20, 2004 deposition states that Harvard Pilgrim was unaware of physician acquisition costs, even though Harvard Pilgrim bought physician-administered drugs directly at ASP. The Farias deposition states that Harvard Pilgrim did not investigate physician acquisition cost. Furthermore, given the contract that Harvard Pilgrim enters into with any given physician or physician group, they would be unable to do anything other than reimburse according to the terms of the contract, in this case at 95% of AWP, the Medicare formula.<sup>164</sup>

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<sup>164</sup> Deposition of Robert C. Farias, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, October 20, 2004, pp. 36-40, 42-43, 51-52, 100-101, 140-141. Because Massachusetts TPPs, like Harvard Pilgrim, entered into contracts with physicians that specify drug reimbursements according to fee schedules based on AWP or 95% of AWP, Defendants knew that those TPPs (Harvard Pilgrim) felt bound by that contract. As a result, physicians knew that their spreads were guaranteed. Even if and when Harvard Pilgrim had become aware of the fact that physicians were receiving large discounts, Harvard Pilgrim would not alter its contractually-established institutional practice regarding negotiated reimbursement rates.

8. ***Institutional Realities May Have Rendered Better Spread Information Useless in Defeating the AWP Inflation Scheme***

119. Even if large sophisticated TPPs institutionally communicated and made use of their substantial **internal information** regarding its internal ASPs (and Mr. Mulrey's and Mr. Farias' depositions suggests that **they do not**), it is unlikely they could have used that information to aggressively negotiate reimbursement rates reflecting its acquisition costs for the simple reason that their acquisition costs will not reflect the acquisition costs of the providers in their network, providers who are most likely smaller provider groups. BCBS/MA provider reimbursement rates are designed to reflect acquisition costs of **the network providers being reimbursed.** BCBS/MA's direct purchases would provide an imprecise signal for the acquisition costs of the relevant providers submitting reimbursement claims. Given the costliness of evaluating this issue, BCBS/MA would rationally use the Medicare AWP-based reimbursement formula for the reasons cited above.

120. Even if large sophisticated TPPs institutionally communicated and made use of their substantial **internal information** regarding their internal ASPs and made use of substantial market monitoring of **external information** to such an extent that they could generate substantially more precise knowledge and expectations regarding the inflated spreads for the many physician-administered drugs in the market for the specific providers in their network, that information would reveal that each drug, by NDC or J-Code had a different spread. In order to make use of that information, the TPPs would need to negotiate with providers different discounts off AWP for each of those drugs, by NDC and/or J-Code.

121. This requirement would make for an accounting nightmare. Discounts would need to be negotiated, **by drug, and perhaps by provider.** The information management

characteristics of the current system would be totally compromised. Recall that Mr. Young correctly observes,

“The use of AWP by commercial Health Plans as a benchmark for expressing reimbursement limitations for prescription drugs dispensed to the plans’ members expanded in the 1980’s. The expanded use corresponded with (i) the growth of private insurance coverage for prescription drugs, (ii) the increased implementation of computer programs to manage the large volume of claims relating to drugs dispensed from retail pharmacies, and (iii) the shift from indemnity type coverage (based on pharmacy or physician ‘charges’) to coverage based on negotiated reimbursement rates (discussed in detail below). **The published benchmark provided a standardized and programmable means of implementing claims processing systems that could handle the wide-ranging discounts negotiated with individual pharmacies for millions of retail pharmacy claims.**” (emphasis added).<sup>165</sup>

122. Deponents agree. In his deposition, Mr. Mulrey of BCBS/MA states that the several reimbursement schedules used by BCBS/MA for physician-administered drugs did not differentiate among physicians, but **rather relied on Medicare as the common basis for reimbursement (emphasis added).**<sup>166</sup> Mickey Brown, Director of Provider Networks at BCBS of Mississippi, discussed the costs and effort involved in undertaking a departure from the current reimbursement system stating that converting to a reimbursement system based on provider acquisition costs would be “a much bigger effort than we’re willing to undertake.”<sup>167</sup>

123. In this case, given the observed herd mentality, the observed Importance of Being Unimportant, the cost-benefit comparison of instituting an untested and quite costly alternative reimbursement scheme for a group of drugs that constitute a small portion of health care costs,

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<sup>165</sup> Young Rebuttal Declaration, ¶ 49.

<sup>166</sup> Mulrey Deposition, pp. 50-64.

<sup>167</sup> Deposition of Mickey Brown, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, March 9, 2005, pp. 67-69.

TPPs have fallen back upon simple rules of thumb which are easy to computerize and are used by all entities in the health care system – discounts off AWP.

- a) The contract discovery I have reviewed to date demonstrates that TPPs have negotiated to reimburse physician-administered drugs at (AWP – 16%) to (AWP + 15%).<sup>168</sup> Reimbursement off AWP (down to – 16%) may reflect reliance upon Medicare practice and procedures; reimbursement above AWP (up to +15%) may reflect reliance upon FDB promotional claims about the meaning of AWP.
- b) This is almost precisely the range found by the Dyckman Survey for the *MedPAC Report*;<sup>169</sup> specifically MedPAC finds AWP ± 15%.
- c) The study conducted by NORC at the University of Chicago and the Health Policy Institute at Georgetown University for the *MedPAC Report*<sup>170</sup> found that “Private payers have followed Medicare, paying physicians from a low of AWP minus 20% to a high of AWP plus 10% .. [and] Insurers, PBMs, and consultants view this ‘spread’ ... largely as profit for the physician.”<sup>171</sup>

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<sup>168</sup> The contracts I reviewed were produced as Defendants’ materials during the Class Certification Phase.

<sup>169</sup> *MedPAC Report*, Table 9-2, which is based upon the survey work of Dyckman Associates. The survey respondents were 33 large private health plans including Blue Cross Blue Shield plans and national managed care plans whose covered lives represented over one-fifth of those with private insurance in the United States (40 million lives).

<sup>170</sup> At p. 3 of the MedPAC report, “Physician-Administered Drugs: Distribution and Payment Issues in the Private Sector,” August 2003. This study conducted by NORC at the University of Chicago (in conjunction with the Health Policy Institute at Georgetown) surveyed a range of stakeholders in the market for physician-administered pharmaceuticals.

<sup>171</sup> These surveys, additional contract data and other evidence demonstrate that AWP was indisputably the basis for reimbursement by members of Class 3. Defendants’ own documents often reference such AWP-based payments, as follows: “Medicare, private payors, and most Medicaid agencies will cover ZOLADEX (goserelin acetate) and the physician services associated with its use. . . Payments will differ among payors but are usually based on the average wholesale price (AWP as listed in the *Red Book*). Though most insurers will not reveal what amount they will pay, it is typically a percentage of the AWP (often 80 percent)” (AZ0233062-106 at AZ0233075).

d) The Court has noted (at p. 64), “In the physician-administered context, the [contract] range is AWP minus 0% to 10%.”

**9. *Providers Had Far Better Information About the Size of Spreads and the Purposes Those Spreads Were Serving. They Were Better Able to Exploit It***

124. Defendants have frequently appealed to “an overwhelming factual record proving that Class 3’s use of AWP was knowing and deliberate.”<sup>172</sup> They have argued that “The members of Class 3, which consists mainly of large sophisticated insurance companies, know exactly what AWP is, and they know what it is not. They know that AWP is a reimbursement benchmark, not an average of provider acquisition costs. They know that AWP is higher than the price paid by the provider.”<sup>173</sup> Certainly the largest TPP in Class 3, BCBS/MA, does not fit their description. Certainly Harvard Pilgrim does not. Which TPPs do?

125. Rather, throughout this matter, it has been clear that providers have had better information than payors, even large sophisticated TPPs. Providers knew ASPs, AWPs, the amounts they were being reimbursed by the prime mover in this market (Medicare), the fact that

<sup>172</sup> *Track 1 Defendants’ Memorandum*, p.1.

<sup>173</sup> *Ibid.* Many payors to which Defendants’ appeal for support do not fit the description of large sophisticated insurance companies. These TPPs fall into three groups:

- TPPs which had no idea of the relationship between AWP and provider acquisition cost (See for examples, the deposition testimony of Jan Cook of BCBS/MA (March 6, 2006, pp. 132-3, 137, 140-1); Mickey Brown of BCBS/Mississippi (March 9, 2005, pp. 66-7, 84-5, 111-2, 125-7); and Kelly Ellston of Union Labor Life Insurance, Co., Inc. (November 23, 2004, pp. 85-6, 89-90), all *In re: Pharmaceutical Industry Average Wholesale Price Litigation*);
- TPPs which believed that AWP was approximately equal to provider acquisition costs (See for example, the deposition testimony of Michael Mulrey of BCBS/MA, *op. cit.* (pp. 79-82, 87, 118); and
- TPPs that understood that AWP was not equal to provider acquisition cost but otherwise had no idea about the relationship (See for examples, the deposition testimony of Steven Fox (March 8, 2006, pp. 146-9, 169-70) and John Killion (January 6, 2006, pp. 137-9) of BCBS/MA; Mike Beaderstadt of John Deere Health Care (September 17, 2004, pp. 46-7, 73); and Joseph Spahn of Anthem BCBS (November 30, 2004, p. 59); (all *In re: Pharmaceutical Industry Average Wholesale Price Litigation*).

TPPs are loathe to second-guess providers' dispensing decisions and reimbursement claims, the fact that FDB characterized FDB AWPs as accurate measures of the acquisition costs of drugs to providers at wholesale, and the fact that most TPPs do indeed generally follow Medicare's reimbursement practices and procedures. Providers are usually offered information from manufacturers comparing excessive "Spreads" or "Returns to Practice" for alternative therapies, precisely to incentivize the providers to move market share (Section III above). The providers are often advised or contractually constrained from sharing that information with anyone else, most importantly the TPPs paying the inflated reimbursements for the physician-administered drugs (Section III above).

126. Large sophisticated payors do not have access to this information. When they do, as demonstrated above they either do not or cannot use that information to effectively negotiate the excessive spreads away. Such litigation as the Lupron and Zoladex litigation make this clear. These two drugs are not the exception.

127. Finally, not only do the providers have the better information, they have greater market power, as noted by Dr. Berndt at ¶ 108 of his February, 2005 Independent Report as follows:

"With physician-administered drugs, health plans/insurers risk losing valued physicians from their specialty networks (with all the implications that has for the competitiveness and relative attractiveness of the plans they offer employers) if they move patients from medical to pharmacy benefits and contract through specialty pharmaceuticals or PBMs for purchasing these [physician-administered] drugs, instead of letting physicians capture the benefits of purchasing the drugs themselves and implicitly reselling them to payors. As a result, payors may not be quite as aggressive in obtaining cost information about these drugs, as they would be were they dealing with pharmacy-dispensed drugs."

Providers simply had all or substantially all of the facts to the manufacturers' scheme and the existence of inflated spreads; TPPs did not.

***10. Manufacturer Marketing Strategies Reveal that TPPs Expectations Were that AWP Provided a Reasonable Expectation of ASP***

128. As developed in Section III above, manufacturers of physician-administered drugs began to promote their products to providers with explicit "Return to Practice" or "Spread" increases, once new competition from a therapeutic or generic manufacturer entered the relevant market. Absent such new product competition, spread competition was unnecessary and most likely not profit maximizing. This fact is made clear by the discovery materials of GSK with respect to Zofran and Kytril (see ¶ 66 above). The use of spread competition and the efforts to cloak that competition from all market entities except for the providers being incentivized also have been discussed.

129. The market context in which this strategy was designed and implemented is the following.

- a) Almost all market participants and payors knew that AWP and WAC were prices (however determined and whatever they meant), off of which reimbursement rates for the drugs at issue here were calculated by members of Class 3.
- b) While some TPPs paid little attention to the meaning of these list prices, the better informed TPPs believed that WAC represented the average acquisition cost (AAC) of pharmacies (retail acquisition cost, or RAC) or providers (provider acquisition cost, or PAC), as attested by Mr. Young and cited above. Although those TPPs that reviewed and relied upon FDB promotion (perhaps it was those promotions that

informed Mr. Mulrey; see ¶ 118.a)) could easily have expected or believed that providers acquired the drugs at issue here at AAC ≈ AWP.

- c) The former TPPs would believe therefore that the average spread earned by providers reimbursed at AWP would be 20 to 25% above acquisition cost. The latter would believe that the average spread earned by providers would be 0% above acquisition cost.
- d) Given the fact that Medicare reimbursement had been understood to be cost-based; given the fact that many physician-administered drugs had been single-source over the 1980s and into the 1990s (see the quote of Dr. Berndt at footnote 153 above); given the fact that Medicare's reimbursement rates for single source Part B drugs was AWP minus (0 – 15%); given the non-transparency of ASP information in this market, indeed even **within TPPs** in this market; and given the herd mentality characterizing TPP reimbursement for physician-administered drugs; it is reasonable to infer that TPPs generally believed that spreads were on the order of 0% – 25% over the Class Period.

130. This inference is confirmed by manufacturer pricing strategies in this matter. When a given manufacturer has historically developed and sold a single-source drug without competitors, it has priced its drugs to providers at ASPs implying spreads within the range of expectations identified above – spreads of 0-25%. When competitors enter the market, price competition occurs (in terms of ASP), price competition that is not passed on to Class 3. At the same time, AWP inflation has occurred, the reimbursement implication of which has been increased prices to Class 3 TPPs.

131. Manufacturers would only undertake such competitive strategies and run such legal risks (see the *Lupron Sentencing Memorandum* and the *OIG Compliance Program Guidance*) if they believed that they would work. To work and to move market share, new entrants had to offer spreads in excess of some amount, confirming that there indeed existed some amount, some baseline spread, which had to be exceeded. Clearly, the spread that had to be exceeded was the spread of the single-source drugs prior to any competition.

132. If the baseline spread of the first single-source drug did not need to be exceeded, the new entrants would not have increased the spreads. If the incumbent, previously-single-source manufacturer did not believe that spread competition was necessary, it would not have increased spreads. The mere fact that spreads had to be increased above the previously single-source baseline, confirms that such a baseline existed.

133. Likewise, manufacturers must have believed that the spreads and spread competition would be compromised by TPPs' market knowledge, information and competition; otherwise, they would not have offered them to providers under constraints of secrecy.

## **11. Conclusions**

134. The argument fails that TPPs generally, and large sophisticated TPPs specifically, had sufficient knowledge to alter and improve their reasonably-held expectation that there was a close relationship between AWP and provider acquisition cost. These TPPs observed this relationship being used for cost reimbursement purposes within the large Medicare Part B regulatory framework; they observed it being employed as a basis for public and private reimbursement for many billions of dollars of self-administered drug products. Such market-wide use and acceptance of AWP-based reimbursement was a basis for spread expectations

Class-wide, expectations upon which TPPs negotiated reimbursement rates with providers.

Those expectations determined the range of equilibrium reimbursement rates negotiated by Class 3 TPPs, reimbursement rates which were disadvantageous.<sup>174</sup>

135. Those expectations and the reimbursement rates negotiated thereby reflected the simple fact that “every commercial transaction involves an element of trust.”<sup>175</sup> Those expectations and the reimbursement rates negotiated thereby reflected the belief that the AWP was a *reasonable sticker price*, not a *sucker price*. As noted by the Court in the Lupron matter:<sup>176</sup>

“Defendants repeatedly assert that they had no duty to disclose what was publicly known to everyone, that is, that the Lupron(R) AWP was a ‘sticker price’ and never intended to reflect the drug’s true average wholesale price. In support of this argument, defendants cite a number of government reports acknowledging that the published AWPs for prescription drugs often exceed their acquisition cost. The argument is ultimately unpersuasive. There is a difference between a sticker price and a sucker price. If one were confronting a modest markup of the actual AWP for Lupron(R) (which 300% is not), intended to make sales of the drug for the treatment of Medicare patients commercially viable (given the 95% of AWP reimbursement rate), it is unlikely that there would have been a government investigation of TAP’s marketing practices. Similarly, if the same inflated AWP had not been used to set reimbursement rates for private purchasers and insurers, the Amended Complaint would not have been filed. The Blues, in their response to defendants’ argument, have it exactly right: ‘If everything [about

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<sup>174</sup> Defendants’ Expert Robert Navarro summarizes this market-wide reliance and the resulting expectations as follows:

“**There is not a workable alternative to the use of benchmark** as a basis for setting reimbursement....Two of the benchmarks used in expressing negotiated reimbursement amounts are the published Average Wholesale Prices (‘AWPs’) and the Maximum Allowable Cost (‘MAC’) lists prepared by health plans and PBMs.” (¶¶ 46-47).

“**AWP is the principal benchmark** used as a basis for expressing pharmacy reimbursement for brand name drugs. ... The health care industry understood [by the 1980s] that the AWP benchmark was set as a standard markup over wholesale acquisition cost (‘WAC’) typically 20-25% for branded drugs. AWP was universally adopted because it was available, known and readily ascertainable.” (¶¶ 48-49).

Declaration of Robert P. Navarro, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action: 01-CV-12257-PBS, October 25, 2004.

<sup>175</sup> See footnote 139, where Daniel McFadden quotes Kenneth Arrow.

<sup>176</sup> *In re: Lupron Marketing and Sales Practices Litigation*, MDL No. 1430, Master File No. 01-CV-10861-RGS, United States District Court for the District of Massachusetts, November 25, 2003.

Lupron(R)] was known to everybody, why did defendants emphasize secrecy?" Blues Memorandum, at 7. Finally, the recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct."

136. In the next Section, I discuss more fully the range of rates negotiated by TPPs based upon these expectations. I also introduce a Yardstick Threshold Spread for a finding of causation and liability that is greater than the upper bound of the range of reimbursement rates that I find. It is therefore conservative as a threshold for causation and liability.

## VII. ANALYSIS OF LIABILITY FOR CLASS 3

### A. Overview

137. Given the discussion in Section VI above, I now discuss how I determine my Yardstick Spread which I use for analyzing and determining causation and liability for Class 3. I employ standard yardstick methods,<sup>177</sup> which the Court accurately describes<sup>178</sup> as follows:

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<sup>177</sup> I note that the use of a "yardstick method" has a long and venerable tradition in economic theory and applied economic analysis. It has been utilized in many contexts including, but by no means being limited to, the following:

- Legal analysis of thresholds for a determination of tacit collusion; see for example, D.A. Yao and S.S. DeSanti [1993], "Game Theory and the Legal Analysis of Tacit Collusion," *Antitrust Bulletin, Symposium on Tacit Collusion*, 38(1).
- Tax-setting behavior by U.S. states; see for example, T. Besley and A. Case [1995], "Incumbent Behavior: Vote-Seeking, Tax-Setting, and Yardstick Competition," *American Economic Review*, 85(1), March.
- Regulating the cost, performance and/or pricing of natural monopolies and public enterprises; see for examples, Roger Sherman [1989], *The Regulation of Monopoly*, Cambridge University Press, pp. 73, 285, 1989; and W.W. Cooper [1943], "The Yardstick for Utility Regulation," *Journal of Political Economy*, 51(3); A. Shleifer [1985], "A Theory of Yardstick Competition," *Rand Journal of Economics*, 16(3); F.M. Scherer [1980], *Industrial Market Structure and Economic Performance*, chapter 18; J. Rosellion and J. Halpern, "Regulatory Reform in Mexico's Natural Gas Industry," World Bank Report, Latin American and the Caribbean Region.
- To strategically manage managerial performance; see for example, Jean Tirole [1995], *The Theory of Industrial Organization*, chapter 2.2; and B.R. Holmstrom and J. Tirole [1989], "The Theory of the Firm," *Handbook of Industrial Organization*, chapter 2, Volume 1.
- To strategically induce research and development; see for example, Jean Tirole [1995], *The Theory of Industrial Organization*, chapter 10.4.

"Hartman intends to calculate the spreads for the drugs allegedly subject to the AWP scheme and compare those spreads to 'but for' spreads, that is,

- Spreads for comparable drugs that are unaffected by the AWP scheme and fraud.
- As a cross-check, he will compare the calculated 'but for' spread with industry-wide surveys.
- In addition, under the 'revealed preferences' method, Hartman will calculate the expected spread by examining the contracts for the drugs affected by the alleged fraud to determine what the parties expected the spread between AWP and the ASP to be, and compare that expected spread with the actual spread. (Hartman Rebuttal ¶ 50 ('Simply stated, economic agents reveal their preferences, and implicitly the information they relied on, by their actual market decisions and behavior.'))" (bullets added).

138. I have undertaken this analysis as follows. First, I have identified single-source comparator pharmaceuticals, both orals and physician-administered, for which data were available to me. As I have noted, based upon Track 1 Manufacturers' own strategic planning (e.g., for GSK and Zofran in ¶ 66), the spreads for these drugs provide measures of spreads untainted by the AWP Inflation Scheme. For context, I have analyzed the evolving therapeutic competition they faced over the period 1989 through the present, to clarify whether and when they were subject to the competition that induced them to participate in the AWP Inflation Scheme. The relevant drugs are introduced and discussed in more detail in Section VII.C.

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- Regulating insurance premia; see for example, Irving H. Plotkin, "Total Rate of Return and the Regulation of Insurance Profits," Arthur D. Little Report, Presented at the May 1979 Meetings of the Casualty Actuarial Society, chapter IV.
  - Analysis of the performance of Social Security; see for example, W.W. Beach and G. G. Davis [1998], "Social Security's Rate of Return: A Reply to Our Critics," Report of the Heritage Center for Data Analysis.

In all of these applications, actual economic or market results and/or behaviors are compared with an appropriate yardstick or set of yardsticks (**i.e., but-for measures**) to determine whether the actual market results and/or behaviors meet certain legal, regulatory and/or managerial standards. My yardstick analysis is used precisely in the same way – to assess whether actual pricing behavior of Defendants met or failed to meet non-fraudulent pricing standards.

<sup>178</sup> Memorandum and Order, pp. 63-65.

The AWP Inflation Scheme was designed and implemented to move market share relative to therapeutic or generic competitors. In the absence of therapeutic competition, a given manufacturer would find it unnecessary **and unprofitable** to increase spreads to move market share;<sup>179</sup> if uniquely efficacious, the clinical profile of the drug would be sufficient to move market sales. Successful “break-through” innovator drugs serve as reasonable yardsticks for “but-for” spreads or baseline spreads, precisely because they reflect the manufacturer’s understanding that AWP Inflation (or Spread Inflation or increased Return to Practice) was unnecessary to move market share for single-source branded drugs reimbursed by Class 3. These spreads were inflated under the Scheme precisely when manufacturer felt it was necessary to manipulate the spread to compete with new market entrants.

139. Second, “as a cross check,” I have extended and discussed above (at ¶ 77) my original review (found in ¶¶ 28-33 of my September 3, 2004 Declaration) of publicly available sources providing market-wide information concerning the relationship between AWP and ASP for branded and generic self-administered and physician-administered drugs. Based upon that review, my preliminary yardstick spreads were 11%-25% in ¶ 30.a) of my September 3, 2004 Declaration.<sup>180</sup> I extend these conclusions above, summarizing my more broadly-based group of publicly available survey materials found in Attachment D to this Testimony and discussed in ¶ 77 above.

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<sup>179</sup> These comparator drugs include unique breakthrough innovator drugs developed for particular clinical uses and competitive innovator drugs that had been unique but came to face therapeutic competition over time. These comparator drugs were either not subject to this litigation, or were subject to this litigation but are included as comparator drugs during that period when they were the single-source unique therapeutic alternative available on the market.

<sup>180</sup> When I hypothesized that rebates could amount to 5% (see ¶ 30.d of my September 3, 2004 Declaration), my estimate of the yardstick spreads became 18%-33%. However, it has been noted that for physician-administered drugs, rebates are usually not paid to providers. Indeed, the Judge has recognized this fact; see *Memorandum and Order*, p. 29. My analysis of Defendants’ rebate data has confirmed this fact. Therefore, the 11-25% range of yardsticks is the appropriate range.

140. Finally, the relevant contract information I have been able to review to date (see ¶¶ 123.a)-123.c) above) demonstrate that TPPs have negotiated to reimburse physician-administered drugs at (AWP – 16%) to (AWP + 15%). It is interesting to note that this is almost precisely the range found by the *MedPAC Report* based upon the Dyckman Survey; specifically MedPAC finds AWP ± 15%. It is consistent with *MedPAC Report* survey performed by NORC at the University of Chicago; specifically, AWP – 20% to AWP + 10%. The Court has noted “In the physician-administered context, the [contract] range is AWP minus 0% to 10%.”

## B. Implementation

141. The basis for my finding of causation and liability is empirical. It requires a comparison of actual spreads with yardstick spreads or a Threshold Yardstick Spread. I conduct my analysis for the remaining Track 1 drugs by calculating the ASPs by NDC for each drug as precisely as the manufacturer data production allows. These ASPs are presented in Attachment G. Given those ASPs, I identify the relevant AWPs, which are also presented in Attachment G.<sup>181</sup> Using the AWP and ASP, I calculate the spread for drug j of Defendant k as  $\text{Spread}_{jk} = (\text{AWP}_{jk} - \text{ASP}_{jk})/\text{ASP}_{jk}$ . These spreads are presented in Attachment G.<sup>182</sup>

Since it is necessary for a manufacturer to increase the spread of the relevant physician-administered drug above what would have been the case absent the fraud in order to implement and benefit from the AWP scheme, I find causation and liability for any NDC of any of these

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<sup>181</sup> I use RedBook throughout for my AWPs, unless such data were unavailable. In that case, I relied upon First DataBank. I note that the discovery materials suggest that Medicare carriers frequently make use of RedBook for their AWPs. It is possible that some of the payor claims data make use of First DataBank, the AWPs of which at times diverge somewhat from those found in RedBook.

<sup>182</sup> The information in Attachment G is presented as follows. Each Table G.1-G.4 is designated for each of the remaining four Track One Defendants in the following respective order: AstraZeneca (AZ), Bristol-Myers (BMS), Johnson & Johnson (J&J) and Schering-Plough (SP). For each firm, the data are presented as follows: Table G.1.a contains the ASPs; Table G.1.b contains the AWPs; and Table G.1.c contains the spreads.

drugs if Equation (1a) of my September 3, 2004 Declaration is found to hold. Specifically the alleged AWP scheme excessively raised reimbursement rates for drug j of Defendant k if

$$(1a) \quad \text{Spread}_{jk} > \text{Spread}_{jk}^{\text{but-for}},$$

where  $\text{Spread}_{jk}^{\text{but-for}}$  is the Yardstick Threshold Spread.

### C. Yardsticks for a Finding of Causation and Liability

142. Equation (1a) explicitly relies upon the notion of yardstick spreads. The source of first importance to me to calculate these yardsticks is the set of all successful “break-through” innovator drugs for which data are available, since that data reveal manufacturers understanding of what the reimbursement market would bear. While I requested of Defendants data for a variety of drugs, I received limited usable data. I have been able to make use of some Defendant data, data and analyses of Defendants’ experts, and other data.

143. Using specific single-source physician-administered drugs, I find the following.

- a) In Attachment H.1, I present AWP and ASP information for Zofran. The data for Zofran NDC 00173044200 are compelling. Zofran launched as the first Serotonin 5-HT3 Blocker (antiemetic), a unique market niche. It did not face therapeutic competition until Kytril launched in 1994. Once Kytril did launch, the manufacturers of each drug clearly used and cloaked their use of spread (as discussed in Section III above) to compete for market share. When GSK faced no competition, it required no spread increases above its baseline spread, which was 18.6%-20% for the three years,

1991-1993. Once therapeutic competition arose, the spreads were increased to compete for market share.<sup>183</sup>

- b) In Attachment H.2, I present the AWPs and ASPs for Taxol from its launch in 1993. At that time, it was the only therapeutic competitor offering Paclitaxel. When it launched, using RedBook AWPs, its spread was 25% and remained at 25-27% from 1994 until 2000, when generic launch induced BMS to pursue spread competition to move market share. Using First DataBank AWPs, when it launched its spread was 20% and remained at 21-22% from 1994 until 2000.
- c) In Attachment H.3, I present the AWPs and ASPs of Blenoxane. Using Red Book AWPs, it launched in 1993 with a spread of about 27% and remained at that level until it faced competition motivating it to increase its spread. Using First DataBank AWPs, it launched in 1993 with a spread of about 22% and remained at that level until it faced competition motivating it to increase its spread.
- d) Using Red Book AWPs, I conclude that the relevant spreads provided by innovator single-source physician-administered drugs that did not require exploitation of the AWP Inflation Scheme to compete range from 18-27%, which I use as a basis for my Yardstick Spread. If I based my Spread Yardstick upon First DataBank AWPs for these drugs, the range would be 18%-22%. All of these spreads are consistent with the understanding of spreads signaled by Medicare reimbursement practices.

144. As cited above (¶ 77), in the course of my analysis for this matter I have reviewed a variety of publicly-available survey research summarizing the “market” information on spreads

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<sup>183</sup> Note that Zofran’s AWPs are equivalent in the RedBook and First DataBank. This is not the case for Taxol and Blenoxane.

for single-source physician-administered drugs, surveys addressed for the most part to CMS/HCFA. For this group, the range of reasonably anticipated spreads found in the survey research is 11%-25%, which corroborates the comparator drugs introduced in ¶ 143 above.

145. As discussed in Section VI above, reimbursement patterns for most physician-administered drugs, whether administered under Medicare coverage or under private commercial payor coverage, are driven primarily by Medicare reimbursement practices. Medicare reimburses at spreads of 0-15% off AWP, which amount to spreads of at most 18% above ASP.

146. Contracts negotiated by commercial payors with provider groups reveal spreads around AWP of ± 15%-20% (see ¶123 above). When reimbursements are based at AWP – 20%, which is the best discount off AWP I find in contract information, this reflects the payor's ability to negotiate to anticipated provider acquisition costs for physician-administered drugs which are, on average, at AWP-ASP spreads of 25%. If payors believe that providers acquire physician-administered drugs at AWP (as did Mr. Mulrey of BCBS/MA for years), then reimbursements at AWP + 15-20% suggests that the reasonable expectation of average spreads was 15-20%.

147. Given the information available, I weigh most heavily the spreads reflected by pricing strategies for single-source physician-administered comparator drugs and the spreads revealed by publicly available survey research for single-source physician-administered drugs.<sup>184</sup>

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<sup>184</sup> There is no real evidence that the yardsticks for TPP price expectations for multi-source physician-administered drugs were *systematically* different than those for single-source physician-administered drugs. There is no survey information of which I am aware that has documented systematic spreads on generic physician-administered pharmaceuticals. Dr. Berndt agrees, stating at ¶ 229 "the literature in the public domain is not helpful in the area of generic drugs administered by physicians." Given the even greater lack of pricing transparency for these drugs, relative to self-administered orals, I find no compelling reason that pricing expectations for generic physician-administered drugs would be more educated (i.e., different) than the observed relationship for single-source physician-administered drugs. Indeed, in light of the discussion in Section V, there is little reason to expect that they would or could be. As a result, I use the same yardstick for liability for all physician-administered drugs, whether single-source or multi-source.

However, as I clarify in Section VII, where I calculate damages, **I do not calculate damages for multi-source physician-administered drugs. Therefore, while I believe this observation to be correct, it has no effect on the**

I conclude that a reasonable range of spreads expected in the market; negotiated into contracts; and untainted by the AWP scheme is 11%-25%, using First DataBank. Using RedBook AWPs, I conclude that a reasonable range of spreads untainted by the AWP scheme is 11%-27%.

148. To be conservative, I choose 30% as my Threshold Yardstick Spread. This spread is greater than the upper bound of the ranges that I have found in my data sources. Hence, it is conservative. Using it, if a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.

149. It is appropriate to proceed by NDC and its related AWP. It is clear from discovery materials, fact evidence and my analysis in the Lupron matter that manufacturers decide to artificially increase the spread for a given NDC relative to other NDCs for strategic reasons. Indeed, I understand that there has been documentation of the temptation to shop NDCs for the highest AWP. Based upon the same body of evidence, I find it is appropriate to proceed by year. Manufacturers alter their promotional strategies across NDCs over relatively short periods of time, frequently less than a year (as I found in the Lupron matter). Hence, the use of annual spreads to capture spread manipulation (when such competition is of shorter duration) will be conservative. The fact evidence certainly indicates that manufacturers strategically increase and decrease the spreads of certain NDCs over short time periods relative to other NDCs, as their marketing strategies and product life cycles evolve. Providers have been demonstrated to reasonably be assumed profit-maximizing actors who bill the most they can for

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**calculation of damages.** Furthermore, despite the fact that publicly-available information suggesting increasing spreads became more prevalent in the latter years of the Damage Period, it does not seem that TPPs were able to act on such information for the reasons cited in Section VI above.

the drug administered. Providers will certainly not bill less than the allowed AWP for a particular NDC.

150. I interpret my 30% Yardstick Threshold as follows.

- a) For all of the reasons developed in Section VI, I find that the market-wide practices and procedures set in place for physician-administered drug reimbursement were sufficiently established and the information required to understand abuses within those practices and procedures was sufficiently non-transparent, that the TPPs who are members of Class 3 simply could not improve their expectations about the signals provided by AWP about ASP. There is no magic competitive force that will drive negotiated reimbursement rates to ASPs. The bargaining equilibrium will be disadvantageous to all members of Class 3.
- b) In the face of this disadvantageous negotiating position and prohibitive costs of acquiring and acting upon information gathered by NDC, TPPs reasonably look to rules of thumb to simplify reimbursement across all physician-administered drugs within standard computerizable algorithms based upon discounts off AWP. Given the herd behavior revealed among TPPs, reliance upon Medicare reimbursement is common, which has reimbursed up to 15% off AWP (implying spreads reflected in negotiating positions of TPPs of 18%).
- c) If this is the starting point of a TPP's negotiations with providers (and it would seem to be) and manufacturers realize this (as they seem to do), manufacturers will certainly offer single source drugs facing no competition to providers at no less than AWP – (18-25%). This is analogous to manufacturers of single-source self-

administered offering pharmacies some margin at retail acquisition costs (RAC) of AWP – 20% = WAC, when TPPs reimburse the pharmacies at AWP – (13%-18%).

- d) Any spread in excess of this level suggests that manufacturers are facing new competitive entrants and have inflated their spread to compete and move market share. Hence, any spread inflated through the AWP Inflation Scheme reveals itself when the spread is in excess of the levels quantified above, at most about 25%.
- e) To be conservative, I have set the threshold at 30%. Any spread in excess of this threshold I take to reveal spread inflation implemented through the AWP Inflation Scheme.
- f) As discussed above, any spread summarizing competitive pricing through spread inflation is not standard pro-consumer competition. The competition benefits the providers and inflates the providers' profits, at the expense of the consumer.

#### **D. Conclusions of the Liability Analysis**

151. Using this yardstick of 30%, I identify in Attachment I when any of the drugs (by NDC and year of liability) of each of the Track One Defendants (by Defendant in Tables I.1-I.4) exceed that threshold for liability. I find that drugs for all four remaining Track One manufacturers do.

#### **VIII. CALCULATION OF AGGREGATE CLASS-WIDE DAMAGES TO CLASS 3**

152. Using methods and data described in Section IX (Discussion of Technical Issues), I calculate the number of units of each subject drug by NDC and Defendant by year reimbursed by members of Class 3, nationally and in Massachusetts. I designate each such amount as  $Q_{jk}$ ,

where j is the designation of the NDC, k is the designation of the Defendant, and I do not include a designation for year to simplify the notation.

153. I implement my damage calculation for all NDCs for each of the four remaining Track 1 Defendants, as requested of the Court. However, as with statutory damages to Class 2, the method is identical for each remaining Defendant.

154. I subject each NDC of each drug of each Defendant to the threshold test for causation and liability identified in Equation (1a) above, where  $\text{Spread}_{jk}^{\text{but-for}} = 30\%$  for each NDC j and Defendant k, for all years of the damages period. Note that the use of the 30% threshold is certainly conservative for much of the damage period (say 1991-2003), when the reimbursement signals sent by Medicare reimbursement were that AWP – (0%-5%) was the approximation to be used for average acquisition cost. At AWP – 5%, the implied spread is 5.3%. Hence, allowing expectation to be reasonably approximated by 30% is conservative indeed.

155. Having identified the drugs (by NDC, Defendant and year) that have been subject to the AWP Inflation Scheme (causation and liability by manufacturer, by NDC and by year), injury as damages are calculated as follows.

- a) For single-source drugs, I use the liability yardstick  $\text{Spread}_{jk}^{\text{but-for}} = 30\%$ . I allow the single-source drugs to remain subject to damages and use the same yardstick for six months after the first generic launch.<sup>185</sup> At that point, I assume multiple generic launches occur, unless I have information to the contrary. Once multiple generics

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<sup>185</sup> This treatment is supported by PBM contracts for reimbursement of self-administered single-source orals (see p. ESI-277-00002070 found in ESI-277-00002066-77) and by the practices of DHHS with respect to the Federal Upper Limit (p. 12 of Attachment D of my September 3, 2004 Declaration).

launch, I assume MAC pricing is introduced and that damages are calculated as discussed immediately below for multi-source drugs.

- b) For multi-source drugs, I assume MAC pricing is in use; I assume that the MAC pricing does not reference AWP; and therefore the drugs are not subject to damages. This is a conservative assumption.<sup>186</sup>

156. I have cited (¶ 147 and footnote 184) my understanding, one shared by Dr. Berndt, that there is no reliable information regarding spreads for generic physician-administered drugs. Absent such information, I have opined that the measure of expectations used for single-source physician-administered drugs is most appropriate for multi-source physician-administered drugs. While Defendants may object to that extrapolation, **it is without effect as a matter of damages to Class 3**, since I simply do not calculate damages for multi-source physician-administered drugs for Class 3, because I cannot explicitly determine whether they were subject to MAC pricing or not. I interpret multi-source competition as implying reliance upon MAC pricing, thereby eliminating a drug from Class 3 damages.

157. I calculate damages for non-Medicare units using the formulation introduced in ¶ 25 of my September 3, 2004 Declaration (at ¶¶ 21-23). Specifically, ignoring the subscripts j and k on the spread above, the actual reimbursement rate allowed by the commercial payors in Class 3 can be derived from the inflated AWP as allowed amount = AA = AWP - x% = (100% -

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<sup>186</sup> These assumptions are conservative for a variety of reasons. For example, MAC pricing frequently references AWP. However, explicit reference to AWP is required by Judge Saris (at p. 74 of her *Memorandum and Order*) for physician-administered multi-source drugs: “In the context of generic physician administered drugs reimbursed through private TPPs, . . . generics will be considered only to the extent that the price in the contract between the TPP and physician is expressly predicated on AWP.” Given the Court’s concern for this issue for Class 3, I exclude any damage calculations for multi-source drugs.

$x\%)*AWP$ , for any  $x\%$ .<sup>187</sup> Then the but-for AA = AA<sub>but-for</sub> = AWP<sub>but-for</sub> -  $x\% = (100\% - x\%)*AWP_{but-for}$ . The injury or overcharge per unit reimbursed is (AA - AA<sub>but-for</sub>) = (100% -  $x\%)*(AWP - AWP_{but-for}) = (100\% - x\%)*(Spread - Spread^{but-for})*ASP$ .

Using this formulation, I calculate aggregate Class 3 (non-Medicare) overcharge damages as follows:

$$(1b) \quad \text{Aggregate overcharge damages} = (AA - AA^{but-for})*\text{total units reimbursed}, \\ = (100\% - 2.5\%)*(Spread - Spread^{but-for})*ASP*Q,$$

where 2.5% represents the average discount off AWP for physician-administered drugs reimbursed in a non-Medicare context by all commercial payors, as surveyed and reported by the *MedPAC Report*,<sup>188</sup> and Q is the total units of the relevant NDC of the relevant drug for the relevant Defendant reimbursed by Class 3.

I calculate non-Medicare overcharge damages for all single-source drugs until multiple generics launch, at which point I assume that MAC is put into effect and I set the overcharge damages to \$0.00 beginning in the following year.

As with the Medicare damage, I first calculate aggregate overcharge damages in the U.S. for all non-Medicare units being reimbursed. I then disaggregate that total to overcharge damages borne by all U.S. consumers (through inflated coinsurance payments and inflated out-of-pocket payments) and overcharge damages borne by all TPPs in the U.S. I finally disaggregate from that national total the overcharge damages to the Massachusetts members of Class 3.

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<sup>187</sup> As noted in ¶ 123 above, the *MedPAC Report* indicates that  $x\%$  can range from ± 15% over the Class. See also the next footnote.

<sup>188</sup> See *MedPAC Report*, Table 9-2. The average weighted (by the number of respondent payors) reimbursement was 97.55%AWP. I round that discount to (100%-2.5%) for ease of calculation and exposition.

158. The damage calculations are reported in Attachment J by Defendant, nationally and for reimbursements in Massachusetts. Table 3 below summarizes these damages for Class 3.

**Table 3.a: Summary of Damages (Nominal \$)**

<b>Company</b>	<b>Class 3: Non-Medicare Damages to Consumers and Third-Party Payors (Nominal \$)</b>	
	<b>National</b>	<b>Massachusetts</b>
AstraZeneca	\$359,455,174	\$9,501,489
Bristol-Myers Squibb	\$56,970,345	\$1,505,899
Johnson & Johnson	\$8,958,163	\$236,791
Schering-Plough	\$10,291,358	\$272,032

**Table 3.b: Summary of Damages (2006 \$)**

<b>Company</b>	<b>Class 3: Non-Medicare Damages to Consumers and Third-Party Payors (2006 \$)</b>	
	<b>National</b>	<b>Massachusetts</b>
AstraZeneca	\$425,829,199	\$11,255,956
Bristol-Myers Squibb	\$67,186,909	\$1,775,954
Johnson & Johnson	\$11,155,281	\$294,868
Schering-Plough	\$14,249,904	\$376,668

## **IX. DISCUSSION OF TECHNICAL ISSUES**

159. A number of technical issues arise in the calculation of aggregate class-wide damages, the discussion of which I have postponed, for expositional ease, until now.

### **A. Variability among Members of Class 3 is Addressed by Accepted Economic Techniques**

160. All markets, without exception, are characterized by variation. Indeed, it is a primary hallmark of the science and practice of microeconomics to account for variability within markets, and by accounting for that variability achieve reasonably accurate aggregate

calculations or estimations of quantifiable information. It may further be said that a significant purpose of applied economics and microeconomics is to explore the variability inherent in marketplaces, explain that variability, and account for it with summary information that enable one to draw meaningful aggregate conclusions about complex economic behaviors.

161. Among the methods employed in order to explore and address variability within a class, subclass or any group of economic individuals or entities is the use of average measures and the calculation of an aggregate damage amount. It must be emphasized, however, that the use of average measures is not an effort to ignore the variability or complexity of the members of a class or subclass. It is in fact a standard statistical method used to directly address that variability in order to calculate meaningful measures and accurate, aggregate outcomes (in these circumstances, an aggregate damage calculation).<sup>189</sup>

162. The concern about variability and averaging is less important for Class 2; they are largely formulaic, as recognized by the Court. For Class 2, the actual reimbursement rate (and the 20% co-insurance amount) has been some percentage of AWP, while the but-for reimbursement rate by the “plain-meaning rule” (and the but-for 20% co-insurance amount) was the ASP to providers.

163. The use of averaging is primarily relevant to Class 3. While an expert must be careful that the averages used in the formulaic methodology are sufficiently representative of the

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<sup>189</sup> In this regard, I can see how the use of the term “average measures” might inappropriately denote a sort of “rounding off” or otherwise avoiding complexity or variability. In the area of applied economics and microeconomics, however, the use of average measures actually enables one, on an aggregate basis, to address and accommodate variability across the members of the class.

This ambiguity perhaps leads the Court to be unduly ambivalent about the use of average measures. For example, the Court states (*Memorandum and Order*, p. 63) “it is not permissible to use methods such as averaging damages to sweep individual issues under the judicial rug.” My use of averaging does not “sweep individual issues under the judicial rug.”

Class being analyzed and for which aggregate damages are being calculated, the use of average measures constitute a standard approach to measuring aggregate damages.<sup>190</sup>

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<sup>190</sup> As I have discussed at some length in my previous Declarations in Support of Class Certification, my approach is used routinely in the scientific literature. See for examples, Daniel Rubinfeld, "Reference Guide on Multiple Regression" (pp. 179-227); Robert E. Hall and Victoria A. Lazear, "Reference Guide on Estimation of Economic Losses in Damages Awards," (pp. 277-332); both found in *Reference Manual on Scientific Evidence*, Second Edition, 2000, Matthew Bender Publishing Co; and Raymond Hartman and Michael Doane, "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," *The Journal of Law, Economics and Organization*, Fall 1987.

Likewise, the approach is used regularly in litigation. In all of the Hatch-Waxman litigation and the Lupron litigation in which I submitted Declarations in support of Class Certification, calculated damages, and/or submitted damage calculations supporting settlement agreements, I have used analogous methods that make use of averages. See, for examples, *In re Terazosin Hydrochloride Antitrust Litigation*, Case No. 99-MDL-1317 Seitz/Garber, United States District Court for the Southern District of Florida; and *Cipro Cases I and II*, Judicial Council Coordination Proceeding Nos. 4154 and 4220 (Superior Court, San Diego County). See also footnotes 2-12 in my September 3, 2004 Declaration. See also *In re Cardizem CD Antitrust Litigation*, Master File No. 98-MD-1278, 200 F.R.D. 326 (E. D. Mich. 2001).

Such methods have been used in calculating aggregate damages in litigation with greater variation among Class members than that revealed here. It is well known that airline ticket prices for a given route can vary widely, certainly by more than the variation I have observed in reimbursement rates among TPPs in Class 3. See for example Borenstein, S. and Rose, N.L. [1994], "Competition and Price Dispersion in the U.S. Airline Industry," *Journal of Political Economy*, 102(4), pp. 653-683. This did not preclude class certification in this industry; see *In re Domestic Air Transp. Antitrust Litig.* 137 F.R.D. 677 (N.D.Ga.1991) where 12.5 million class members purchased tickets for an array of different routes, at diverse times, at a multitude of varying prices, and on diverse terms. Also see, *In re Sumitomo Copper Litig.* 182 F.R.D. 85 (S.D.N.Y. 1998). A class consisting of two subclasses, purchasers and sellers of Comex copper futures contracts over a two-year period, was certified despite differing interests between long and short subclasses: "[in the Second Circuit] factual differences in the amount of damages, date, size or manner of purchase, the type of purchaser, the presence of both purchasers and sellers, and other concerns will not defeat class action certification when plaintiffs allege that the same unlawful course of conduct affected all members of the proposed class" (citations omitted).

Such methods have been employed by Defendants' experts Young, Gaier, and White in their consulting or academic research. For example, in his deposition (Deposition of Dr. Halbert L. White, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, Rough Draft, November 29, 2004), Dr. White testified that he has performed such damage calculations in other litigation. In his discussion of consulting work in re the class of direct purchasers of vitamins (*In re Vitamins Antitrust Litigation*), he describes the methodology that he used to calculate damages as follows:

"[W]e modeled the price of specific vitamin products. The goal there was to obtain estimates of what prices would have been in the absence of the admitted conduct. Based upon that estimate of the but for price, one can then calculate a difference between the actual and the but for, which can be and was used to estimate aggregate damages for all of the direct action plaintiffs: The modeling also used the information on the but for price from the market to relate the prices paid by individual plaintiffs to the market price so that an analysis of plaintiff by plaintiff damages could be constructed" (p. 40).

For identification and discussion of more examples, see Attachment F of my December 16, 2004 Rebuttal Declaration in this matter.

164. In this matter, there will be variation among payors in their ability to negotiate reimbursement rates relative to the perceived AWP, although not much when the negotiation involves discounts off AWP, as recognized by the Court.<sup>191</sup> The use of averages overcomes the concerns about such variability. More importantly, it must be noted that the variation among Class members in this matter is dwarfed considerably by the size of artificial AWP inflation. Specifically, the variation in negotiated reimbursement rates relative to the actual artificially inflated AWP is reasonably bounded by  $\pm 15\%$ . The size of the AWP inflation (measured by the “Spread” as implemented in Attachment G to this Testimony) is 25%-1000%, with some measures exceeding 1000%.<sup>192</sup> Hence, **the measure of injury** (i.e., the artificial inflation of the AWP) **overwhelms the measure of variation among Class members** in their ability to negotiate reimbursement rates. In the face of such measures of overall damage to the Class as a whole, the existing amount of variation among Class members does not undermine the reasonableness of the aggregate damages calculation.

165. Let me make these opinions more intuitive with a graphical presentation, which I present in Figures 12.A-12.C.

- a) The Court,<sup>193</sup> other experts, other survey research and I agree that reimbursement rates negotiated by TPPs with providers for physician-administered drugs are related to AWP.

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<sup>191</sup> The Court has noted, “In the physician-administered context, the [contract] range is AWP minus 0% to 10%” (p. 64, *Memorandum and Order*).

<sup>192</sup> If the spreads and the yardstick are measured relative to AWP rather than ASP, they will be smaller than those reported here. However, they will still be greater than (often an order of magnitude greater than) a yardstick measured relative to AWP.

<sup>193</sup> At p. 65 of the *Memorandum and Order*, the Judge refers to one aspect of this earlier analysis as follows, “Hartman ... proposes using each TPP’s actual contract reimbursement rate (e.g., AWP minus 15%) to determine what rate the TPP would have paid in the but-for world, on the assumption that the actual contract rate takes into

- The *MedPAC Report* demonstrates TPPs reimburse for physician administered drugs on average at 97.5%\*AWP, with the range of the percentage being (85%-115%), using the Dyckman survey results. The NORC at the University of Chicago survey cited by the *MedPAC Report* finds that payors reimburse within the range of (80%-110%)\*AWP, a finding consistent with the Dyckman Survey.
  - Discovery materials indicate that providers submit claims to TPPs for reimbursement based upon the AWP. For example, contracts have allowed amounts set at AWP  $\pm$  15%.
  - Hence, claims for reimbursement are distributed around the actual (i.e., **artificially inflated** AWP = AWP<sub>ai</sub>) as portrayed in Figure 12.B.<sup>194</sup>
- b) The distribution of the reimbursement rates allowed on all claims ( $r^{ai}$ ) relative to AWP<sub>ai</sub>, is summarized by their average in Figure 12.B,  $r^{ai}_{avg}$ . Note that the variation of negotiated reimbursement rates around the artificially inflated AWP (AWP<sub>ai</sub>) is relatively small ( $\pm$  15%-20%), as suggested by fact evidence.  $r^{ai}_f$  represents the reimbursement negotiated by a favored TPP, that is, one with a larger number of insured lives, greater informational sophistication, and therefore somewhat better expectations (if such a one exists; certainly BCBS/MA does not qualify), which can thereby negotiate a better discount of AWP.  $r^{ai}_{lf}$  represents the reimbursement rates negotiated by a less favored TPP, that is, a less informed TPP with fewer insured lives and perhaps no information or expectations, which is therefore less well-positioned to negotiate a favorable reimbursement rate. Indeed, this TPP may pay more than AWP, perhaps believing that AWP  $\approx$  ASP, as FDB asserted until 2005.

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account the knowledge and market power of each TPP. (Hartman Decl. attach. F ¶¶ 4-5; Hartman Rebuttal ¶¶ 54, 58, fig. 1-C.)”

<sup>194</sup> As the Court will recognize, Figures 12.A-12.C are adaptations to physician-administered drugs of Figures 1.A-1.C of my December 16, 2004 Rebuttal Declaration.

- c) The distribution of TPPs by size, sophistication and expectations has been revealed by the range of negotiated discounts off AWP noted in ¶¶ 165.a) and 165.b) above.
- d) However, as the Court has stated (at p. 60), while “some TPPs may have greater sophistication with respect to the existence of spreads because they purchase self-administered drugs [an opinion which, I note, is not supported by the evidence], ... there is no evidence that TPPs ... know of the mega-spreads that exist for these drugs.”
- e) Note the existence of such “mega-spreads” indicates that the actual ASP is **substantially below** the actual AWP (i.e.,  $(AWP_{ai} - ASP)/ASP$  is 50% to 1000%) and **substantially below** the actual distribution of reimbursement rates (depicted in Figure 12.B).
- f) If the AWP related to the ASP in ways **reasonably expected** by the TPPs and measured by the range of spreads used to set my Threshold Yardstick Spread (i.e., as the but-for AWP =  $AWP_{but-for} = AWP_{bf}$ ), then the bell-shaped distribution of reimbursement rates would be those found in Figure 12.A, with a distribution of reimbursement rates for favored and less favored TPPs, as described above. This distribution can also be summarized by an average, which is also standard statistical practice.
- g) In both cases, this distribution summarizes the variation in reimbursement rates negotiated by TPP members of Class 3. This distribution is narrow relative to the “mega-spreads.” Indeed, both distributions summarizing variation among Class

members are smaller than the difference in AWPs induced by the alleged inflation;

$$\text{AWP}_{\text{ai}} > \text{AWP}_{\text{bf}}.$$
<sup>195</sup>

- h) Aggregate damages are calculated using the averages in Figure 12.C, that is  $(r_{\text{avg}}^{\text{ai}} - r_{\text{avg}})$  times the number of claims reimbursed.
- i) Implementation of this method for the calculation of aggregate damages to the Class 3 is implemented using Equation (1b) in Section VIII above.
- j) Damages to particular payors, such as a less favored payor and a favored payor can also be calculated in Figure 12.C as
  - Overcharge damages per unit of drug reimbursed for the favored payor =  $r_{\text{f}}^{\text{ai}} - r_{\text{f}}$ . (See the area designated by the red arrow.)
  - Overcharge damages per unit of drug reimbursed for the less favored payor =  $r_{\text{lf}}^{\text{ai}} - r_{\text{lf}}$ . (See the area designated by the blue arrow.)
  - And of course, overcharge damages for the average payor are  $r_{\text{avg}}^{\text{ai}} - r_{\text{avg}}$ . (See the area designated by the purple arrow.)

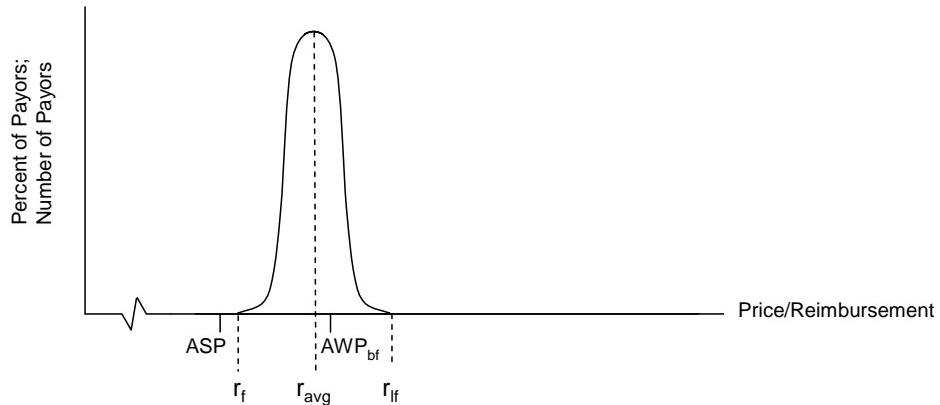
166. This use of average measures of injury in this way will provide an accurate calculation of the summation of individual payor damages if the averages are calculated correctly.<sup>196</sup> This use of measures for individual groups of favored and less favored payors will allow for calculation of damages for groups of payors within Class 3.

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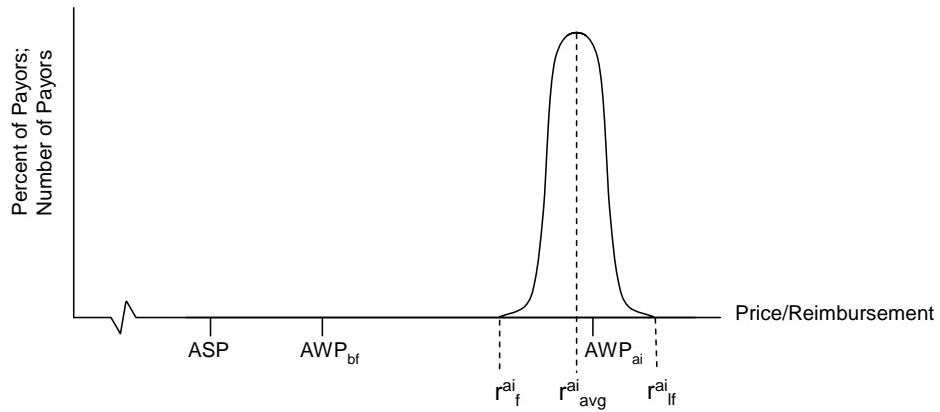
<sup>195</sup> Note that if the actual spread is 1000% and the but-for spread is 30%, then the AWP inflation relative to the drug acquisition cost (ASP) is 970%. Specifically, if  $(\text{AWP}_{\text{ai}} - \text{ASP})/\text{ASP} = 10$  and  $(\text{AWP}_{\text{bf}} - \text{ASP})/\text{ASP} = 0.30$ , then  $(\text{AWP}_{\text{ai}} - \text{AWP}_{\text{bf}})/\text{ASP} = 9.70$  (or 970%).

<sup>196</sup> I demonstrate this fact in Attachment F of my September 3, 2004 Declaration. In the real world, use of average measures of injury will provide a sufficiently precise calculation of the summation of individual payor damages.

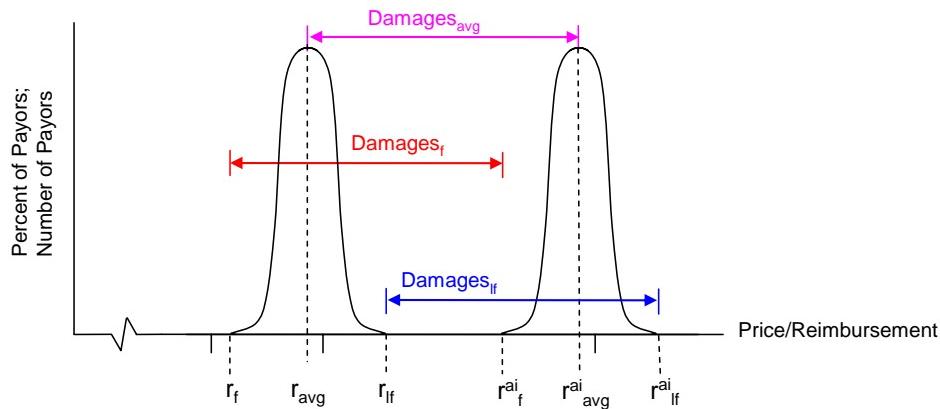
**Figure 12.A**



**Figure 12.B**



**Figure 12.C**



**B. The Use of J-Codes by Commercial Payors Does Not Interfere with Accurate Calculation of Aggregate Class-Wide Damages**

167. The use of J-Codes for invoicing payors for physician-administered drugs can be readily accommodated by my formulaic damage methodology.

168. Both Judge Saris and Dr. Berndt<sup>197</sup> have noted that the use of J-Codes for invoicing physician-administered drugs under medical benefit claims has obfuscated the reimbursement process; made drug prices much less transparent and difficult to monitor; and has created “opportunities for mischief and abuse” which have been the impetus for this litigation and have resulted “in the egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians.”<sup>198</sup> I agree, as I have developed in my ¶ 113 above.

169. This Court has articulated concern that the complexity of the J-Code system, which arguably has facilitated the AWP pricing scheme, may simultaneously make it difficult or impossible to accurately calculate the economic injury in the form of damages resulting from the scheme.<sup>199</sup>

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<sup>197</sup> In his Report, Dr. Berndt concludes at ¶186, “In the market environment for physician-administered drugs, a variety of forces -- the relatively small dollar amounts they involve, the ambiguity of whether the claims stem from the medical or drug component of the health benefit, the troublesome relationships with providers who act as both buyers and sellers (and prescribers and dispensers) of physician-administered drugs, and the J-code claims system that has obfuscated the utilization and pricing of individual drug products and confounded close monitoring – have together contributed instead to a system lacking checks and balances and inviting abuse. Some of that abuse has already been uncovered in this Court and elsewhere.”

<sup>198</sup> At ¶199, ¶204 of Dr. Berndt’s Report.

<sup>199</sup> Specifically, the Court has stated (at pp. 69-70)

“[T]he independent expert, Berndt, expresses concern with Hartman’s analysis because of the poor quality of the data available. He cites ‘accounting ambiguities’ concerning whether physician-administered drugs were covered as medical or drug benefits and a J-Code classification system that ‘obfuscated true transaction prices and utilization’ in concluding that ‘the quality of general information concerning actual prices for physician-administered services is likely to have been very poor.’ (Berndt ¶ 228.) He also points out that the ‘high touch, high cost’ characteristics of physician administered drugs imply that the statistical variance from any sample of information could be ‘very high.’ (Berndt ¶ 229.) To exacerbate the difficulties in deciphering the data, the literature in the public domain is not helpful in the area of generic drugs administered by physicians. (Berndt ¶ 229.) In a

170. While it would be unfortunate indeed that one of the devices by which Defendants effectuated their fraudulent pricing scheme and thereby injured consumers would ultimately be the device behind which Defendants could hide from prosecution and payment of compensable damages for that injury, the situation is neither as dire as Mr. Young asserts<sup>200</sup> nor as uncertain as Dr. Berndt suggests.<sup>201</sup>

171. Since the source of the J- or Q-Codes for physician-administered drugs is the CMS, it is useful to review a recent Medicare Claims Processing Manual,<sup>202</sup> specifically that chapter relevant to claims calculation and submission (Chapter 17), keeping in mind that reimbursement practices have changed over time. Under Chapter 17 "Crosswalk to Old Manuals," Section 10 "Payment Rules for Drugs and Biologicals" it states

- a) "Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) for the service with which they are billed. Certain drugs, however, are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks. The classes of drugs required to have 'pass through' payments made under the Balanced Budget

follow-up memorandum, Dr. Berndt states that he expects that the cross-walking between the five-digit J-Code and the eleven-digit NDC code that will be necessary to track actual physician administered drug utilization and unit prices 'is more likely to be feasible and reliable for the more recently introduced and typically more expensive biotech physician-administered drugs, and much less likely to be feasible and reliable for older, and in particular, multi-source off-patent and generic products.' (Berndt Mem. of Aug. 9, 2005 at 2.) He adds that cross-walking will be less feasible for reimbursements made prior to 2000. (*Id.*)"

<sup>200</sup> At ¶ 142 of his Rebuttal Declaration, Mr. Young states "The [commercial payor] reimbursement data [for physician administered drugs] also show that a significant volume of transactions do not occur at a constant relationship to AWP. (See Exhibit 15)"

<sup>201</sup> At ¶ 197 of his Report, Dr. Berndt states, "This raises the issue of how easy and reliable it is to crosswalk from J-code to NDC-code claims. ... Just how labor intensive crosswalking will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point. This is an important issue that merits thoughtful and concise clarification by both Plaintiffs' and Defendants' experts."

<sup>202</sup> Taken directly from [http://www.cms.hhs.gov/manuals/104\\_claims/clm104index.asp](http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp); accessed December, 2005.

Refinement Act of 1999 (BBRA) have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. The CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate.”

- b) “If the dosage given is not a multiple of the Health Insurance Common Procedure Coding System (HCPCS) code [that is, a J-or Q-Code], the provider rounds to the next highest unit in the HCPCS description for the code. If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount.” In Section 20.2, those drugs reimbursed under a HCPCS or J Code are to be filed using “the unit of measure by which such HCPCS code is defined” which has been called the “Fundamental Billing Unit.”<sup>203</sup> In Section 20.5.4, “Find the Strength and Dosage,” methods to identify and use the “fundamental billing unit” are provided.
- c) “Drugs and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., RedBook, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician’s service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003 changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP.”<sup>204</sup> In Section 20.2, those drugs for which reimbursement claims are submitted and paid that do not rely upon the “fundamental billing unit” are included in the Not otherwise classified (NOC) Drug Pricing File, for which CMS furnishes a NOC SDP file which contains the NDC code and drug name for every NOC drug under the HCPCS Code (J-Code) for which claims are submitted to local carriers; the unit of measure by which such drug is covered; and the Medicare allowed amount.
- d) According to Section 20.4, “Calculation of the AWP”, “Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately. A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources ...”

172. The implications of these statutory codifications for my damage analysis are the following.

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<sup>203</sup> For greater discussion of reliance upon the Fundamental Billing Unit, see footnote 59 and ¶¶ 30-31 of my December 16, 2004 Rebuttal Declaration.

<sup>204</sup> There is some greater refinement of percentages off AWP for certain drugs, but the relationship is always set by the Reference Manual and by statute. See also footnote 46 above.

a) Some amount of total units of each of the drugs that are subject to this litigation were dispensed through the hospital out-patient setting during some portion of the Class Period and the coinsurance amounts for those drugs were submitted as reimbursement claims (under Medicare reimbursement practices discussed in ¶ 171.a) above) to Class members. Some portion (20%) of this coinsurance (which should be billed as the actual acquisition cost) would be counted and included as damages.

Note, however, the following:

- As discussed in Section VIII.C below, I exclude from Class damages **all units sold to hospitals**, even if some of those units are dispensed in an out-patient setting and reimbursed in part by Class members. This exclusion applies to those units with coinsurance amounts. My aggregate damages calculations therefore will be conservative for the affected Classes.
- Reimbursements for these coinsurance amounts would appear in commercial payor claims data as relatively unpredictable and perhaps seemingly random amounts. It is likely that many of such claims appear in the reimbursement claims data of the commercial payors put forward by Dr. Gaier and Mr. Young in their Rebuttal Declarations, which introduce considerable variation which is not relevant to my calculation of damages.
- Since I exclude these units from the total units subject to my damage analysis, these types of claims are also excluded from the analysis and any analytic difficulties introduced are eliminated.

- b) The majority of the remaining claims are determined by the AWP of the NDC administered or the AWP of the multiples of the fundamental unit administered.
- c) When commercial payors are reimbursing as supplemental Medicare payors, those reimbursement claims will be 20% of some proportion of AWP (100%, 95% or 85%, depending upon the relevant year of the Class Period). The presence of such claims in commercial payor claims data bases introduces dispersion in claims data, which should not be interpreted as suggesting that claims are unrelated to AWP.

173. I agree with Dr. Berndt's statement in his August 9, 2005 Memorandum to Judge Saris: "Whether the crosswalking will be sufficiently reliable and comprehensive in the class certification context remains I think an open empirical issue." In approaching this empirically, I focus on the period prior to 2000, precisely because that time period is mentioned to be of concern (see footnotes 199 and 201 above).

While I have not received all commercial payor data that I had requested, I have been able to make use of commercial payor data provided by Defendants' experts. For example, I have taken the claims data from one such payor, BCBS KC, and examined the amounts allowed (AA) for reimbursement on claims for one physician-administered drug for each of the five original Track One Defendants. I present the results of my analysis in Table 4 below. I note the following.

- a) The allowed amounts found in the claims data for 1998<sup>205</sup> are either:
  - An identifiable percentage of AWP, clearly well within the range found by the 2003 *MedPAC Report*, Table 9.2.
  - Unclearly related to AWP (designated as "unclear"). I interpret these claims to reflect coinsurance amounts on hospital out-patient administration (¶ 171.a) above) for the most part, which I exclude from my analysis and damage calculations.
  - For four of the five drugs, allowed amounts are integer multiples of 90-105% of AWP,<sup>206</sup> indicating that the commercial payor reimbursed a total dollar amount related to an improperly reported quantity of units. Damages on such claims would be attributable to the entire allowed amount, regardless of the units reported.
  - Some percentage of each of the five drugs reported allowed amounts that were zero (\$0.00). The explanations possible for this finding are the following:

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<sup>205</sup> For Remicade, the earliest year for which claims were available was 2000. The reasons are stated in Table 4.

<sup>206</sup> Specifically, the percentages of claims by drug are Zoladex (0%), Taxol (9%), Zofran (9%), Remicade (14%), and Intron A (36%). Note that this range is conservative, since MedPAC finds that the range across payors is 85% to 115%. If I expanded the range here, the number of "unclear" claims would be reduced even further.

- A claim was submitted by a provider with incomplete billing/diagnosis information and the amount allowed was \$0.00. The claim bounced back to the provider; the provider corrected the mistaken information; the claim was resubmitted and paid. In this case, this original claim and the observed allowed amount (\$0.00) do not reflect a real reimbursement and are irrelevant, albeit they introduce spurious variation in the claims data base.
  - A claim was submitted by a provider with complete and correct information and was indeed rejected; that is, the amount allowed was \$0.00. In this case, the insured (who is part of one of the relevant Classes) pays the claim and the damages are borne by that coinsurance payor and are calculated as part of damages to that payor group. Alternatively, the provider is not reimbursed and the claim remains unpaid. I have found no evidence suggesting that this situation occurs to any measurable extent.
- b) Based upon these data, I find no evidence to defeat the conclusion that substantially all claims for which allowed amounts are reimbursed will be included in my aggregate damage calculation. **Those claims that reflect reimbursements for coinsurance for hospital out-patient administration (i.e., “% unclear”) will not be included in the units subject to the aggregate damages calculation. The number of units subject to the damage analysis but for which reimbursement is actually not paid by some Class member (“zero dollar amount”) is small.**

174. The analysis in Table 4, which focuses upon the variation of allowed amounts for a single year (1998) for BCBS KC for the five drugs can be extended even further into the past. I do so in Attachments K.1 and K.2, for one of the drugs in Table 4, Zoladex. I do so graphically, using claims data submitted by Defendants’ experts for BCBS KC. I note the following.

- a) Dr. Berndt has proffered the opinion (see footnotes 199 and 201 above) that the crosswalk between J-Codes and NDCs will more likely be feasible for more recently

introduced drugs and less likely to be feasible for older drugs, particularly those dispensed and claimed prior to 2000.

- b) However, as made clear in Table 4, the crosswalk is certainly feasible for 1998. I can relate the amounts allowed by J-Code in 1998 to AWPs for all or substantially all claims that are relevant to the damage analysis for each remaining Track One Defendant.
- c) Furthermore, in Attachment K.1 and K.2, the dispersion and variation in reimbursements for Zoladex in 1998 are certainly less than in those years after 2000; that is, in those years in which the CMS HCPCS crosswalks were more formally codified and in which Dr. Berndt believes the crosswalks are more reliable.
- d) Attachment K.1 summarizes **all** claims data for BCBS of KC for J-Code 9092 (Zoladex).

Note the following:

- The dispersion over all claims is substantial.
  - However, the dispersion diminishes going backward from 2004 to 1995.
  - The dispersion includes many claims that are zero, which should be excluded as discussed above. The dispersion includes many claims that are multiples of distinct percentages of AWP.
  - Using Table 4, when I eliminate the claims for zero reimbursement and I correct the claims for the integer multiples of a standard percentage range of AWP (90-105%), I obtain Attachment K.2.
  - In Attachment K.2, the overall variation is diminished considerably. At the same time, the identical pattern of diminishing variation going backward from 2004 to 1995 remains.
- e) In both cases, I find that the variation and dispersion in reimbursements in 1994-1997 **was even less than in 1998 and was substantially less than it was during the period 2000-2004.**

f) Hence, I find nothing in these claims data that suggest that BCBS KC was unable to relate (and reimburse) submitted claims to the AWP of the relevant NDC in 1998 specifically and prior to 2000 generally.

175. In Attachment L, I provide a sample of evidentiary materials including contracts and letters between commercial payors and providers and deposition testimony of representatives of commercial payors. These materials demonstrate reliance by commercial payors upon AWPs for the fundamental billing unit or for the actual NDCs. Such reliance would produce results analogous to those found in Table 4 above.

In addition, contracts introduced by Mr. Young<sup>207</sup> include the specific J-Code Q0136, which is for Procrit (J&J). There are 14 NDCs listed in the recent CMS crosswalk (8 if one counts only the first nine digits) for Procrit/Q0136.<sup>208</sup> The other class of drugs singled out in the contracts is chemotherapy drugs. Temodar, doxorubicin (Rubex), bleomycin, carboplatin, Paraplatin, cisplatin, Cytoxan, Etoposide/Vepesid, and paclitaxel are all examples of chemotherapy drugs with multiple NDCs per J-Code. Albuterol is another drug I have examined that has many NDCs per J-Code. The contracts almost always refer reimbursement to the AWP, which either applies to the AWP of the specific NDC of the drug administered as part of the medical service or to the AWP of the fundamental billing unit of the J-Code.

176. Clearly, the most recent CMS crosswalks are comprehensive and allow for a detailed description and quantification of the relationship between J-Codes and the related multiple NDCs and their respective AWPs. However, the information that has been published in

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<sup>207</sup> See contracts between Humana and Kansas City Oncology and Hematology Group, HUM00839-912; Humana "Physician Group Participation Agreement," HUM01151-01214; HUM01867-01921; Blue Cross Blue Shield of Kansas City Letter Agreement and Memo for Chemotherapy Drug Pricing, KC0003265-66.

<sup>208</sup> For the most recent crosswalk, see <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

these recent crosswalks were being gathered over the years since 2000<sup>209</sup> and have consistently improved commercial payors ability to cross-walk and relate reimbursement claims to the NDCs/AWPs of the physician-administered drugs involved in the related medical procedures. Finally, the analyses that I have presented in Table 4 and Attachment K demonstrate that commercial payors could readily distinguish the relevant NDCs and AWPs for determination of the amount allowed for a physician-administered drug for a given medical benefit before 2000.

177. Finally, and importantly, the feasibility of crosswalking J-Codes to NDCs has been examined and successfully implemented by the OIG much earlier than 2000. For example, **in a May 1996 publication analyzing the appropriateness of 1994 Medicare prescription drug allowances,**<sup>210</sup> the OIG undertook an analysis which found the following:

- “Medicare presently pays for most prescription drugs based on the Average Wholesale Price of the drug product” (p. ii).
- “Drugs are billed to the Medicare program based on codes developed by HCFA. These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand or generic version of the drug was administered” (p. ii).
- “The drug code list [that was analyzed] primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used for diagnostic imaging” (p. 3).

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<sup>209</sup> As stated by the CMS in its February 7, 2003 Program Memorandum [to] Carriers, “On August 17, 2000, we published a final rule (65 FR 50311) that implements standards for electronic transactions in accordance with the administrative simplification provisions of HIPAA. This rule became effective on October 16, 2000. HIPAA required Medicare and other insurers to be capable of processing claims using NDCs for drugs within 24 months (by no later than October 1, 2002) after the effective date of the final rule. A subsequent law, the Administrative Simplification Compliance Act (ASCA) of December 2001, allowed covered entities to request an extension until October 16, 2003 for implementation.”

<sup>210</sup> Department of Health and Human Services, Office of Inspector General, “Appropriateness of Medicare Prescription Drug Allowances,” May, 1996, OEI-03-95-00420.

- [In the analysis,] “we needed to link Medicare’s HCPCS codes to NDC codes. This involved matching the drug product and dosage defined by the HCPCS code with the corresponding NDC codes for all available brand and generic versions of the drug” (p. 3). The analysis focused upon 17 HCPCS codes.
- “For 10 of the 17 codes, the process of linking the HCPCS code with corresponding NDC codes was relatively easy to accomplish since the HCPCS codes represented single-source drugs where only one brand name drug was available. For these drugs, we collected NDC codes that matched the drug dosage requirements outlined in the HCPCS code description” (p. 4).
- “For the remaining seven drug codes, we needed to determine all of the versions (both brand and generic) of the drugs produced by different manufacturers that met the HCPCS dosage requirement” (p. 4).

I conclude that the crosswalk from HCPCS Codes to NDC codes was considered “relatively easy” for single-source drugs as early as 1994. For multi-source drugs, the crosswalk was more data intensive but still possible.<sup>211</sup> It involved identifying all versions, including generic and branded, of the drugs meeting the HCPCS dosage requirement. I know that a crosswalk is possible, because I have implemented one in my damage calculations, as discussed in Section IV above.

178. I conclude that for all or substantially all of the J-Codes relevant to this analysis, there are multiple NDCs. I conclude from the contracts, discovery materials and publicly available information I have reviewed that for all NDCs within all J-Codes relevant to the Classes, the provider has been contractually required to and did submit a claim for reimbursement for some percentage of AWP, unless the provider were a hospital outpatient facility billing the coinsurance amount. I conclude that commercial payors were able to distinguish the amount allowed on the relevant medical benefit claim and paid an allowed

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<sup>211</sup> 6 of the 15 drugs analyzed in this litigation were single source throughout the Damage Period; of the remaining 9, 3 were single-source for a substantial portion of the Damage Period. The six drugs that went multi-source by 1994 are the following: Cytoxan injectable (in 1983); Rubex (in 1990); generic albuterol sulfate (in 1992); Proventil (in 1992); generic perphenazine (in 1993); and Vepesid (in 1994).

amount that related to the AWP of the relevant NDC or of the fundamental billing unit for the J-Code for all drugs relevant to the Classes. In some cases, the allowed amount was equal to integer multiples of some percentage of AWP, indicating that the allowed amount reflected  $x\% * \text{AWP} * \text{number of units}$ . Damage calculations for such multiple unit claims are straightforward, as discussed below (Section IX.D). When reimbursement was paid for coinsurance on an out-patient administration, I do not include those units in my damage analysis.<sup>212</sup>

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<sup>212</sup> Parenthetically, I further conclude that when there are multiple NDCs for a J-Code and when coinsurance on hospital out-patient amounts, zero amounts and MediGap-type amounts for the 20% Medicare co-insurance are included, of course there will be a large variation in reported reimbursement rates many of which will appear to be unrelated to the AWP for a single NDC. This is precisely the problem inherent in the analyses of Mr. Young and Dr. Gaier, as I explicitly pointed out in my December 16, 2004 Rebuttal Declaration (¶¶ 29-31 and 34.c)). For the reasons presented in this Section, I conclude, as before, that their presentations are spurious and misleading.

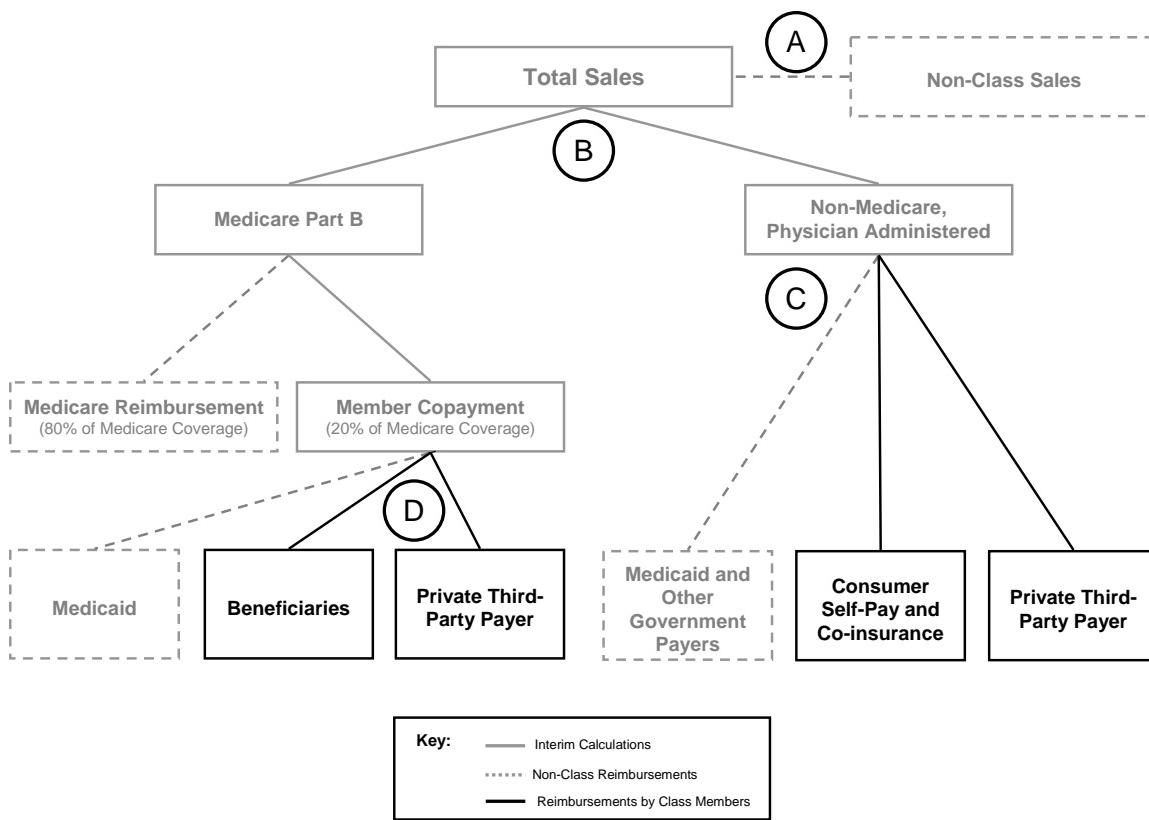
**Table 4: Blue Cross Blue Shield of Kansas City****1998 Medical Claims Data**

<b>Drug name</b>	<b>Distribution of Allowed Amounts</b>
Zoladex (AZ) J-Code examined = J9202	12%: zero dollar amount 27%: 94% of AWP 44%: 95% of AWP 9%: 100% of AWP 8%: Unclear
Taxol (BMS) J-Code examined = J9265	19%: zero dollar amount 16%: 95% of AWP (FDB) 40%: 100% of AWP (FDB) 9%: 104% of AWP (FDB); 100% of AWP RedBook 9%: appear to have errors in units; that is, allowed amounts were integer multiples of 90% to 105% of AWP. 8%: Unclear
Zofran (GSK) J-Code examined = J2405	11%: zero dollar amount 15%: 95% of AWP 47%: 98% of AWP 2%: 100% of AWP 5%: 105/6% of AWP 9%: Appear to have errors in units; that is, allowed amounts were integer multiples of 90% to 105% of AWP. 11%: Unclear
Remicade (JJ) J-Code examined = J1745 <b>Note:</b> Because Remicade claims begin to appear in January 2000, calendar year 2000 was used rather than 1998.	36%: zero dollar amount 37%: 90% of AWP 7%: 95% of AWP 2%: 100% of AWP 14%: Appear to have errors in units; that is, allowed amounts were integer multiples of 90% or 105% of AWP. 4%: Unclear
Intron A (SP) J-Code examined = J9214	7%: zero dollar amount 17%: 95% of AWP 11%: 100% of AWP 24%: 103% of AWP 36%: Appear to have errors in units; that is, allowed amounts were integer multiples of 95% or 100% of AWP. 5%: Unclear

### C. Calculation of the Units Subject to Damages for Each Class

179. A schematic diagram of the flow of units to Medicare and non-Medicare payors subject to the damage analysis is presented in Figure 13. There are four important analytic nodes in the Figure, Node A through Node D.

**Figure 13: Schematic of Sales and Reimbursement by Sub-Class**



180. At the start of my analysis of liability and damages, I integrate all sales, chargeback and rebate data (provided to date) for all physician-administered and Medicare Part B covered drugs from each of the four remaining Track One Defendants. At the time of the submission of this Testimony, these data were fairly complete for the years for which the data

were received. However, the data were not complete for all years of the Class Period. I identify where data were not provided and how I accommodated the damage calculations appropriately in the notes to the relevant damage tables in Attachment J.

181. Broadly speaking, I use the identifiers for customer name, type, and class of trade to exclude, at Node A, all direct units sold to such entities as hospitals, government entities, managed care dispensaries, and those units distributed through wholesalers which are not later distributed to the physician providers who in turn administer to the Class. Those units not excluded by this process are those distributed to physicians, physician groups, oncology groups, clinics, long-term care facilities, nursing homes and certain others. A more precise taxonomy is presented in the notes of Attachment J. When I exclude those units distributed to entities who are not providers to Sub-Class members, I also exclude the related chargebacks and rebates. As a result, the ASPs I present in Attachment G are based upon invoiced sales data, price offsets, chargebacks and rebates on units distributed solely to the relevant Classes.

182. Having identified those units (and their ASPs) relevant to the Classes as a whole, I differentiate, at Node B, those units distributed through providers to Medicare Part B patients and those distributed to non-Medicare patients. This differentiation has been based on survey data summarizing method of payment for procedures at physicians' offices. The two major sources of these data are the National Ambulatory Medical Care Survey (NAMCS) data<sup>213</sup> and

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<sup>213</sup> The National Ambulatory Medical Care Survey (NAMCS) is a widely-used public data set which provides information on the characteristics of the patients (including their insurance) and the providers that use drugs in ambulatory settings. The NAMCS is a national probability sample survey conducted by the Division of Health Care Statistics, National Center for Health Statistics (NCHS), and the Centers for Disease Control and Prevention (CDC). A national sample of office-based physicians provides data on patients' office visits. I have data for 1993-2003 for the drugs in this matter for which data are available.

the IMS National Disease and Therapeutic Index (NDTI) data.<sup>214</sup> Having differentiated those units that are reimbursed by Medicare Part B as the primary insurer and those that are reimbursed by non-Medicare payors, I calculate, at Node C, the extent to which the non-Medicare reimbursements are borne as TPP reimbursements, as co-insurance payments and by other non-Class payors (e.g., Medicaid and other governmental entities, which are of course excluded from Class damages). At Node D, I calculate the portion of the 20% Medicare copay that is reimbursed by TPPs providing Medicare supplemental insurance and that portion paid by consumers. I also exclude the portion paid by Medicaid. At both Node C and D, I rely upon existing survey analyses of these payment patterns.<sup>215</sup>

183. I implement my formulaic damage methodology for each manufacturer, as requested by the Court.<sup>216</sup> However, my analysis demonstrates that implementation is identical for each Defendant.

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<sup>214</sup> The IMS National Disease and Therapeutic Index (NDTI) Data is an office-based survey also summarizing for each physician-administered/Part B drug the method of payment (insurer), the manufacturer, the form (e.g., injectible, tablets, etc.), and the strength (e.g. 15 mg, 30 mg, etc.). I requested these data from each Defendant.

<sup>215</sup> See footnotes 213 and 214 above. NAMCS data were used for BMS; NDTI data were use for AZ, J&J and Schering-Plough. For specificity, see Attachment J.5.

<sup>216</sup> With respect to Class 1, Judge Saris opined (at p. 57) that it is appropriate to disaggregate that Sub-Class by Track One Manufacturer.

“With respect to Medicare Part B consumer patients making copayments, it is cost effective to focus the litigation in one forum, and one case will promote a uniformity of results appropriate for a nationwide reimbursement program. However, from a manageability point of view, it is appropriate to have subclasses of consumers for the drugs of each manufacturer group. Therefore, there will be five subclasses, one for each Track One group. The Court defers deciding whether to hold a separate trial with respect to each manufacturer group.”

I assume that the Judge had intended to extend this disaggregation to Classes 2 and 3.

**D. Calculation of Damages by NDC is Equivalent to Calculation by Payors through J-Codes**

184. I have used manufacturer sales data to calculate overcharge damages, which are incurred by the Class members as a result of inflated reimbursement payments to providers. The question arises: Does the use of manufacturer data provide an accurate calculation of overcharges in payor reimbursements to providers? The answer is yes.

185. Manufacturer data are delineated by NDC. The damage calculations in Sections IV and VIII demonstrate the ease with which the crosswalk between J-Codes and NDCs can be accomplished, confirming the finding of the OIG from 1996 for 1994 Medicare claims (see ¶ 177 above). For single-source drugs, all NDCs, including the NDC of the fundamental billing unit are readily available. Claims for reimbursement are calculated as percentages of the relevant AWP; the but-for AWP is calculated using the relevant ASP. For multi-source drugs, the data requirements are somewhat more onerous; however, it is straightforward to identify all the relevant generic and branded alternative NDCs, their AWPs, and the but-for AWPs.<sup>217</sup>

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<sup>217</sup> More specifically, for Medicare and non-Medicare damages, the crosswalk between J-Codes and NDCs has been demonstrated to be particularly easy for single-source drugs. The NDCs by J-Code are listed; the providers can access those NDCs and AWPs; the payors can review those NDCs and AWPs. Calculation of damages for these drugs is straightforward and formulaic.

For multi-source drugs under Medicare Part B, I identify when any Class drug went generic (i.e., became multi-source), all relevant available generics possible, their AWPs (from RedBook) and the median of their AWPs for the period 1991 through 2003. This median AWP is the reimbursement alternative to ASP for any multi-source drug sold by Defendants and reimbursed by the Medicare Classes 1 & 2 during the period 1991-1997. Over 1998-2003, the alternative to ASP is the lesser of 95% of the median generic AWP or 95% of the least expensive brand name AWP (also available through RedBook or First DataBank). Hence, the data requirements are clear and the data are readily available from publicly-available sources. With the amendments altering reimbursement for multi-source drugs under Medicare beginning January 1, 2004, the reimbursement alternatives to ASP rely upon the lesser of the actual AWPs as of April 1, 2003 of the median generic and branded versions as of April 1, 2003.

For non-Medicare reimbursement of physician-administered drugs, I exclude all units from damages for all drugs that have been or have become multi-source (i.e., the year after generic launch). As discussed above, because I have found that commercial payors are slow to implement this MAC pricing rule, I believe this procedure to be conservative from the point of view of aggregate damage calculations.

186. Payor claims data are delineated by J-Codes. The use of manufacturer data to measure overcharges at the claims level therefore assumes the following: first, that providers do submit claims for the physician-administered drugs that they have purchased in the provision the relevant medical service; second, that the providers are sufficiently profit-maximizing to bill not less than the amount allowed by NDC; third, that providers use NDCs to submit claims to payors, principally by reporting the relevant AWPs and units administered (which will be denominated for the actual NDC or the NDC related to the fundamental billing unit); and fourth, that payors have reimbursed according to the AWP provisions of the Medicare statutes and the payment practices and procedures identified in fact discovery and in survey research (e.g., particularly the 1996 OIG Report (see ¶ 177) above and the *MedPAC Report*), which are based upon NDC-specific data and/or data for the fundamental billing unit. The first two assumptions are based upon rational economic behavior. I have corroborated the latter two assumptions using claims data made available by Defendant experts (see my Table 4). Those data demonstrate that claims relevant for damages<sup>218</sup> are reported as standard percentages of AWP or integer multiples of standard percentages of AWP.<sup>219</sup>

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<sup>218</sup> That is, excluding claims for \$0.00 and for amounts unrelated to AWP (i.e., that summarize coinsurance for out-patient hospital physician administered drug administration).

<sup>219</sup> When a claim is submitted by a provider and reimbursed by a payor in terms of a J-Code, price and quantity administered are included in the claim (see Table 4 above). The claimed amount and quantity is delineated in AWP and units by NDC or by fundamental billing units (which is sometimes a specific NDC). Multiple NDC units or fundamental billing units reflect multiple units produced by the manufacturer.

In some cases, the claims request reimbursement for amounts that are integer multiples of some percentage of AWP, as clarified in Table 4, reflecting an error in the quantity reported. However, since the claimed amount is a multiple of the relevant percentage of one of the AWPs, the logical conclusion is that the total dollar amount is correct but the quantity misstated in the claim. The use of manufacturer data avoids that misstatement; the fact that the claimed amount is an integer multiple of a percentage of the AWP indicates that the claimed amount properly takes the quantity into account.

### E. Schering Intron A

187. I have been asked by Counsel to the Plaintiffs to explain why it is appropriate to include Intron A (“Intron”), a drug manufactured by Schering-Plough, as a physician-administered drug and/or a Medicare Part B drug in this Testimony.<sup>220</sup>

188. Based upon my review of Healthcare Common Procedure Coding System (HCPCS) crosswalk tables provided by the Centers for Medicare and Medicaid Services (CMS) on their website, I find that many Intron NDCs have been issued a J-Code. This suggests that the drug is covered by Medicare Part B, may be physician administered, and is therefore an appropriate Subject Drug. Though some NDCs were not explicitly listed as having an assigned J-Code in the information available to me, I determined that the presentation of some of these NDCs was sufficiently similar to the NDCs that do appear in the crosswalk to assume that many Intron NDCs were covered at some point in time under Medicare Part B.

189. However, Schering-Plough has stated that a set of Intron NDCs are indicated for self-administration only.<sup>221</sup> To be conservative, I have excluded these NDCs from my damages calculations. Nevertheless, note that some of these NDCs have in fact been assigned the J-Code J9214, suggesting Medicare Part B coverage. As just one example, Intron NDC 00085-1235-01 is described by Schering-Plough as being exclusively self-administered and is subject to the

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<sup>220</sup> See Declaration of Raymond S. Hartman Opposing the Schering-Plough Corporation’s Motion to Strike Certain Subject Drugs: Intron A, July 7, 2006. Note that this Declaration refers to my previous damage calculations wherein all Intron A NDCs were included. To be conservative in this Direct Testimony, I have now excluded a subset of these NDCs as described in the section above.

<sup>221</sup> See Memorandum in Support of Schering-Plough Corporation’s Motion to Strike Certain Subject Drugs, June 23, 2006 (hereafter *Intron Memorandum*). See also the Declaration of Jack Micali, attached as Exhibit B to the *Memorandum* (hereafter *Intron Exhibit B*). Note that the following Intron NDCs are not subject to the motion to strike and remain in my damages calculation: 00085-0689-01, 00085-1110-01, 00085-0285-02, 00085-0571-02, 00085-0571-06 and 00085-0539-01. The first five NDCs are characterized as both self-administered and physician-administered (see *Intron Exhibit B*, ¶ 9), whereas the last is characterized as physician-administered (*Intron Exhibit B*, ¶ 10).

motion to strike. Yet this NDC is listed in HCPCS crosswalk tables as having a J-Code of J9214 (see Attachment M to this Testimony) and therefore may be covered by Medicare Part B.<sup>222</sup>

190. I also exclude those NDCs characterized as mostly self-administered and only sometimes physician-administered and which are also subject to the motion to strike. However, the Intron NDC 00085-1133-01, as one example, is also listed in HCPCS crosswalk tables as having a J-Code of J9214 (see Attachment M) and is therefore covered by Medicare Part B.<sup>223</sup>

Again, it is conservative to exclude these NDCs.

191. Schering-Plough lists some Intron NDCs that it admits are commonly physician-administered. Though Schering-Plough does not seek to strike these NDCs at this time, they have reserved the right to do so in the future. It should be noted that some of these NDCs, such as 00085-1110-01, are also found as J9214 on HCPCS crosswalk tables (see Attachment M)<sup>224</sup> for Medicare Part B coverage. These NDCs remain in my damages calculations.

In summary, based on my review of HCPCS crosswalk tables that match Intron NDCs with a specific J-Code, I conclude that, in general, Intron is covered by Medicare Part B, can be physician-administered, and is properly included in the List of Subject Drugs. However, to be conservative, I exclude those Intron NDCs characterized as always or almost always self-administered.

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<sup>222</sup> See the *Intron Memorandum* and *Intron Exhibit B*, ¶ 7. Other NDCs in this category that appear in HCPCS crosswalk tables as J9214 are 00085-1242-01, 00085-1254-01 and 00085-1168-01.

<sup>223</sup> See the *Ibid.*, ¶ 8. The NDC 00085-1179-02 is also listed in this category and also appears in HCPCS crosswalk tables as J9214.

<sup>224</sup> See the *Ibid.*, ¶ 9. The NDC 00085-0571-02 is also listed in this category and also appears in HCPCS crosswalk tables as J9214.

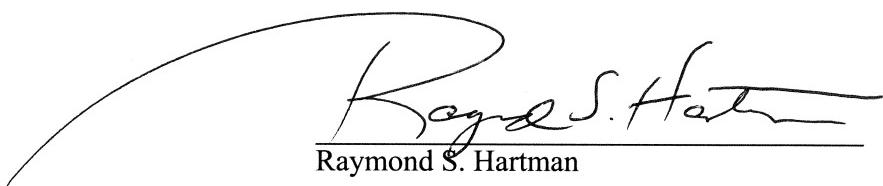
## X. SUMMARY AND CONCLUSIONS

192. The formulaic methodology implemented in this Declaration is based upon sound economic theory and quantitative methods, a valid yardstick approach and a sufficiently complete incorporation of the realities of the business and regulatory practices determining the markets for the administration of and reimbursement for physician-administered drugs.

193. I have implemented my formulaic methodology for the demonstration of causation and liability for Class 3, and having determined liability on an NDC basis annually, I have calculated of aggregate Class-wide damages for Classes 2 and 3. Damages for Class 3 are calculated only for those drugs for which liability was demonstrated. I have found that all four remaining Defendants were liable for artificially inflating the AWPs of some of their drugs for some portion of the Damage Period with respect to Class 3. I have found that the amount of damages is substantial, overall and for each Defendant.

194. I have also found that the structure and approach of the formulaic methodology is the same for all drugs and all four remaining Defendants.

I declare that the foregoing is true and under penalty of perjury.

  
Raymond S. Hartman

11/1/06      CAMBRIDGE, MA.  
Date and Place of Execution

**Attachment A: Curriculum Vitae**

April 2006

**Raymond S. Hartman**  
*Curriculum Vita*

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**DEGREES**

B.A. (MAGNA CUM LAUDE) Princeton University 1969  
M.S. Massachusetts Institute of Technology 1971  
Ph.D. Massachusetts Institute of Technology 1977

**Ph.D. DISSERTATION**

An Oligopolistic Pricing Model of the U.S. Copper Industry (MIT, 1977)

**HONORS, SCHOLARSHIPS, AND FELLOWSHIPS**

1969-71 National Science Foundation Fellowship to MIT  
1965-69 Alfred P. Sloan Scholarship to Princeton  
1969 Woodrow Wilson Fellowship Honorable Mention  
1965 National Merit Scholarship Finalist

**RESEARCH AND TEACHING INTERESTS**

Econometrics/Statistics  
The Economics of Regulated Industries  
Energy and Environmental Economics  
Microeconomics  
Industrial Organization  
Law and Economics

## POSITIONS

1967-1969	Research Staff, Financial Research Center and Center for Economic Research, Princeton University
1970	Research Staff, Board of Governors, Federal Reserve Board, Washington, DC
1972-1992	Consultant and Staff Economist, Arthur D. Little, Inc.
1977-1984	Research Faculty, Massachusetts Institute of Technology
1977-1983	Assistant Professor, Department of Economics, Boston University
1983-1989	Associate Professor, Department of Economics, Boston University
1983-1988	Principal & Academic Principal, The Analysis Group
1988-1993	Visiting Associate Professor/Visiting Faculty, Boalt School of Law, University of California, Berkeley
1988-1995	Founding Principal, The Law and Economics Consulting Group
1995-1996	Vice President, Charles River Associates
1996-1999	Senior Consultant, Charles River Associates
1996-2000	Director, Cambridge Economics, Inc.
2000-2004	Special Consultant, Lexecon Inc.
1997-	Director and President, Greylock McKinnon Associates

## OTHER PROFESSIONAL ACTIVITIES

Research Referee, *Bell/Rand Journal of Economics, Resources Policy, IPC Science and Technology Press, Management Science, Land Economics, Science, Energy Journal, Applied Economics, Econometrica, Review of Economics and Statistics, Journal of Business and Economic Statistics, International Economic Review, Journal of Economics and Management Strategy, Pakistan Journal of Applied Economics, Journal of Health Economics, American Economic Review, Review of Industrial Organization*

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## PAPERS IN PROGRESS

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"Market Definition and Pharmaceutical Market Competition," with Richard Frank and Haiden Huskamp

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Hartman, "A Critical Review of the Delmarva 1981-2000 Load Forecast," with James C. O'Keefe, Arthur D. Little Working Paper, September 1981, Arthur D. Little, San Francisco.

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"Estimation of Hedonic Supply Curves For Residential Water Heaters Using Technical Data and Federal Testing Guidelines," with Alan Cox and Mary Litterman, MIT Energy Laboratory Working Paper #MIT-EL 82-037WP, June 1982.

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## **EXPERIENCE IN CONSULTING AND EXPERT TESTIMONY**

### **Overview of Qualifications**

Dr. Hartman is an economist specializing in microeconomics, econometrics and the study of industrial organization. Microeconomics is the science used to analyze and characterize the behavior of groups of consumers and producers that constitute markets. Econometrics is a science that makes use of mathematics and statistics to measure and quantify economic behavior and economic phenomena in markets. The study of industrial organization makes use of both microeconomic theory and econometrics. It focuses upon the structure, conduct and performance of the participants (consumers and producing firms) in markets and industries, for the purposes of predicting behavior and addressing such policy issues as antitrust, regulation and industrial policy.

He has taught economics, conducted economic research and provided economic consulting in his areas of specialization for thirty-five years. He taught economics as an Assistant Professor and Associate Professor within the Department of Economics at Boston University over the period 1977-1988. He taught economics as a Visiting Associate Professor and member of the Visiting Faculty at the School of Law, Boalt Hall, University of California at Berkeley over the period 1988-1993. He was a member of the research faculty at MIT over the period 1977-1982, during which time he conducted research in energy markets for the United States Department of Energy. During the same time, he declined the offer of a Visiting Assistant Professorship within the Department of Applied Economics at MIT, and instead lectured on a selective basis. Since 1971, he has consulted to federal and state governmental bodies, private corporations, law firms, consulting companies, research organizations and international lending organizations. He has been and continues to be a research referee for a variety of academic journals, including the top academic journals in the country. He is the author of more than 100 refereed journal articles, book chapters and research/consulting reports.

He has submitted oral and written testimony before federal and state courts of law and regulatory commissions. His testimony as an expert witness has addressed anticompetitive behavior, merger efficiencies, breach of contract, employment discrimination, patent infringement, class certification and the estimation of damages in a variety of markets and industries including, but not limited to, the pharmaceutical industry, the health care services industry, the electric power industry, the banking industry, the agrochemical industry, the copper industry, the defense industry, the cable TV industry, the tobacco industry, the electrical and mechanical carbon products industry, the medical devices industry and the construction industry. He has consulted to counsel on litigation matters in a broader array of markets.

While his experience has been broadly-based across industries, two industries/markets have been primary subjects of substantial consulting, research and litigation support.

### **Experience in Energy Markets and Regulated Industries**

Since 1977, Dr. Hartman's expertise and experience have involved regulated industries generally and the markets for electric power and natural gas specifically. His consulting and/or litigation assignments have included load forecasting, evaluation of conservation and load management programs, econometric cost analysis, analysis of revenue requirements and rate-making, analysis of value of service reliability, the analysis of mergers and acquisitions, analysis of industry restructuring, analysis of manipulation of spot and future prices in energy markets, and analysis of contract damages arising from DOE's partial breach of the Standard Contract regarding storage of nuclear waste. In these assignments, Dr. Hartman has consulted for such clients as Arizona Public Service, the Pacific Gas and Electric Company, the Southern California Edison Company, the Southern California Gas Company, the San Diego Gas and Electric Company, Portland General Electric Company, Bonneville Power Administration, General Public Utilities, Northeast Utilities, Niagara Mohawk Power Corporation, the Delmarva Power Corporation, Florida Power Corporation, Sithe Energies, the California Energy Commission and Public Utilities Commission, the Missouri Public Service Commission, the Rhode Island Division of Public Utilities, the Attorney General of the State of Massachusetts, the Electric Power Research Institute, the Gas Research Institute, the U.S. Department of Energy, the U.S. Department of Justice, the World Bank, and the governments of Indonesia and Thailand. He has consulted for a number of other clients whose identity must remain confidential.

## Experience in Health Care and Pharmaceutical Markets

Over the past 10 years, Dr. Hartman has participated as testifying or consulting expert in a wide array of matters related to health-care markets generally and, more specifically, markets for medical devices and pharmaceutical products. For examples, working with a team of health care experts, he submitted written testimony assessing and measuring the impacts of smoking on Medicaid health care costs in the Commonwealth of Massachusetts. He submitted testimony analyzing the competitive impacts upon and damages to a class of dental laboratories caused by the restrictive dealer practices of a dominant U.S. manufacturer of medical prostheses - false teeth. He consulted to the group of wholesaler defendants in the Brand-Name Prescription Drugs Antitrust Litigation, addressing issues of wholesaler pricing across classes of trade. He consulted to counsel to a manufacturer of cardiovascular stents and other related devices in a variety of patent infringement matters, addressing such issues as competition, market penetration of new products and economic damages arising from patent infringement. He consulted for one group of private plaintiffs in the antitrust matter regarding the prescription drugs lorazepam & clorazepate and for the Federal Trade Commission in the matter of Hoechst Marion Roussel, Inc., Carderm Capital L.P. and Andrx Corporation concerning antitrust claims involving the prescription drug Cardizem CD. That consultation addressed issues of market definition, product competition, class certification and damage estimation. He consulted to counsel on the matter of damages to the class of direct purchasers of the prescription drug Taxol and on the matter of damages to the class of indirect end-payer purchasers of the prescription drugs K-Dur, Augmentin, Bextra, Celebrex and Vioxx. He submitted testimony addressing class certification, liability and/or damages for the class of end-payer purchasers in antitrust or RICO litigation concerning the prescription drugs Hytrin, BuSpar, Relafen, Lupron, Premarin, Cipro in the states of New York and California and in the United States, and Neurontin in the United States and Pennsylvania. In the MDL AWP litigation, he submitted testimony in support of the certification of the class of end-payer purchasers of those pharmaceutical products produced by AstraZeneca, the Bristol-Myers Squibb Group, the Johnson & Johnson Group, the GlaxoSmithKline Group and the Schering Plough Group that were alleged to have been the subject of a scheme to fraudulently inflate their Average Wholesale Price (AWP); he subsequently submitted testimony supporting findings of causation, liability and the calculation of damages for those end-payer groups for which class certification was granted. He has consulted to and/or submitted testimony for the Offices of the Attorneys General for the states of New York, Connecticut, Montana and Nevada in analogous matters. His testimony has been the basis for the certification of class in a variety of these matters. His testimony has been the basis for approval supporting settlement agreements in a variety of these and other pharmaceutical matters.

## Specific Assignments

1972-1975: In consultation with Arthur D. Little, Inc., Dr. Hartman developed economic impact models to assess the effects of environmental regulations upon the U.S. pollution abatement equipment industry and upon a particular U.S. copper smelting company.

1972-1975: In consultation with Arthur D. Little, Inc., Dr. Hartman developed economic models to assess the regional macroeconomic and industrial impacts of alternative strategies to promote tourism-related industries. The models were used in the United States by the states of Maryland and Maine and for the Philadelphia Bicentennial Commission. Internationally, the models were used by the Ministry of Planning of Mexico to assess the national and regional importance of tourism coming into Acapulco.

1976-1977: Consultation with Arthur D. Little, Inc. for the U.S. Environmental Protection Agency. The effort involved the design, estimation and implementation of an econometric simulation model that was used to assess the impact of pollution abatement legislation on the U.S. copper industry. The model was designed to incorporate engineering cost estimates attributable to the abatement legislation while accounting for the noncompetitive pricing behavior in the industry. The model was used to evaluate and revise proposed abatement legislation. This analysis was the basis for Dr. Hartman's Ph.D. dissertation and several of his publications.

1977-1982: Working as the testifying expert, Dr. Hartman analyzed the presence of a price-fixing conspiracy among the major U.S. copper producers during the 1970's. His testimony addressed issues of liability and developed a model of damages. See

Affidavit to United States District Court for the Southern District of New York, J.N. Futia Co., Inc., Plaintiff, Against Phelps Dodge Corporation, et al., Defendants, 78 Civ. 4547 (ADS), 1978.

Deposition for United States District Court, Southern District of New York for Reading Industries, Inc., et al. (Plaintiffs) against Kennecott Copper Corporation, et al. (Defendants), 17 Civ. 1736 (MEL), 1982.

1979: Working for the California Energy Commission, Dr. Hartman developed and presented a Statement of Opinion and Critical Review of Selected Energy End-Use Models and Proposed Specifications for PG&E End-Use Modeling Efforts before the California Energy Commission Hearings on Utility Construction and Siting, November 26-30, 1979.

1984: Testifying expert for the class of all individuals who employed the services of members of Massachusetts Furniture and Piano Movers Association. The analysis developed an econometric model to assist in certifying the class and measuring the damages common to that class. See

Affidavit to United States District Court for the District of Massachusetts in the Matter of Kenett Corporation et al v. Massachusetts Furniture and Piano Movers Association Inc. et al, May 1984, Civil Action No. 82-140-Z.

1984-1986: In consultation with the U. S. Postal Service, Dr. Hartman identified appropriate econometric methods for analysis of the determinants of Postal Service costs. The particular methods he suggested were "hedonic" cost techniques, which are specifically designed to account for the fact that both increased levels of production and improved product attributes increase costs. The techniques assisted the Postal Service in quantification of the cost impacts of the attributes of service quality for alternative classes of service. For example, the techniques allowed for estimation of the differential cost impacts of alternative service priorities, size and weight attributes of the various classes of mail.

He later applied these techniques for a group of second class mailers. The analysis was introduced before the Postal Service Commission to assess whether proposed postal rate changes reflected actual costs.

1984-1986: The development of econometrically-based strategic planning models, which allow for estimation of the effects on corporate profits of alternative product design and pricing strategies. The models allow for examining specific design strategies by explicitly incorporating detailed product attributes. The models were developed for Westin Hotels and Shell Oil. The Westin models have been implemented into an interactive PC tool that facilitates pricing decisions at the front desk.

1985: For analysis presented before the International Trade Commission, Dr. Hartman helped develop and estimate a model to evaluate the domestic effects of importation of certain synthetic aramid fibers. The analysis was used in adjudicating an international patent infringement complaint.

1985-1986: Dr. Hartman participated in an analysis of one of the nation's largest mutual funds. The study was undertaken as part of a class action alleging inappropriate management fees. The study assessed competition in the money market mutual fund industry. It measured investors' sensitivity to changes in yield and to the level of services provided. It also statistically identified the determinants of the costs of providing mutual fund services.

1985-1986: The development for GTE Laboratories of econometric demand models for analysis and measurement of the determinants of demand for telecommunications services. The models explicitly address the separate customer decisions to subscribe to one of several telecommunications carriers and the demand for telecommunications services, conditional upon the subscription decision. The analysis was employed by GTE to assist their subsidiary, GTE Sprint, in the design of marketable services, where the services were differentiated by tariff, perceived service quality, provider reputation, and specialized customer services. The analysis is summarized in the paper

"Estimation of Household Preferences for Long Distance Telecommunications Carrier", Journal of Regulatory Economics, Volume 6, 1994.

1985-Present: Dr. Hartman has performed a variety of economic damage analyses in cases of personal injury, wrongful injury and wrongful death. He has worked for both plaintiff and defendant. He has been deposed in such matters as recently as 1995.

1986: For a major natural gas pipeline, preparation of an analysis of the effects of natural gas deregulation as proposed in the Federal Energy Regulatory Commission's Notice of Proposed Rulemaking No. 436.

1986-1987: Working for the class of owners of selected General Motors' X Cars and VW Rabbits, Dr. Hartman specified and estimated econometric models that assisted in the certification of class and estimation of class damages. The damages flowed directly from allegedly-concealed design flaws in these automobiles. The methods are described in

"The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," with M. Doane, The Journal of Law, Economics and Organization, Fall, 1987.

1986-1987: Development of damage models for litigation in high technology industries. The models were developed in several cases. One involved alleged patent infringement by a major Japanese semiconductor firm, and the second involved market foreclosure of a domestic minicomputer emulator. In these efforts, Dr. Hartman developed econometric models to estimate the market potential, absent the violation, for the particular product foreclosed or whose patent was infringed. The methods are described generically in

"Product Emulation Strategies in the Presence of Reputation Effects and Network Externalities: Some Evidence from the Minicomputer Industry," with D. Teece, Economics of Innovation and New Technology, Volume 1, 1990.

1987: Analysis of the competitive effects of relaxing the restrictions on the Bell Regional Operating Companies regarding their vertical extension upstream into equipment manufacture and downstream into the provision of selected telecommunication services. The study was introduced before Judge Greene in the triennial review of the divestiture of the Bell operating companies from AT&T.

1987-1988: For a major gas utility, participation in analysis of the economic effects arising if bypass of an existing pipeline were allowed by state and federal regulation. The analysis developed methods for assessing when competitive bypass is socially desirable. The analysis also developed and used an econometric model to simulate the effects of bypass on demand and prices.

1988: Analysis of the competitive effects the acquisition of trade secrets through the predatory hiring of a competitor's essential labor force. See

Analysis submitted in testimony in the case Universal Analytics Inc. v. MacNeil Schwendler, Corp.

1988-1989: As part of their proposed acquisition of Public Service of New Hampshire, Dr. Hartman was retained by Northeast Utilities, Inc. to develop and estimate load forecasting models. The models were used to assess the demand implications of alternative rate assumptions proposed as part of the acquisition. The forecasts were introduced as part of Northeast Utilities' filings before the bankruptcy court, the state public utility commissions, the SEC and the FERC.

1989: As part of major antitrust litigation against the leading vendors of airline computer reservation systems, Dr. Hartman helped develop liability analysis and models for the estimation of damages.

1989: As a proposed testifying expert for Parnelli Jones, Inc., Dr. Hartman analyzed the antitrust implications of Firestone's retail trade practices, particularly alleged vertical and horizontal restraints of trade. He designed damage models for the alleged violations.

1989 - Present: Dr. Hartman has performed and continues to perform the market analyses required for Hart-Scott-Rodino applications and second requests supporting mergers and acquisitions in a variety of industries, including specialty chemicals, airlines, health care and medical diagnostic products, and energy products and services.

1989-1990: Dr. Hartman participated as a principal investigator and testifying expert for the Division of RatePayer Advocates of the California Public Utility Commission in an analysis of the economic and legal implications of the proposed merger between Southern California Edison Company and San Diego Gas and Electric Company. Dr. Hartman's responsibilities included overall study design, econometric analysis of scale and scope economies arising with the merger, and analysis of efficiencies purportedly arising with the coordination of the demand-side management programs of the two utilities. His direct and surrebuttal testimony is found in

California Public Utilities Commission, Division of Rate Payer Advocates, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Volume V, Chapter II, Application 88-12-035, February, 1990, Exhibit 10,500; and

California Public Utilities Commission, Division of Rate Payer Advocates, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Surrebuttal: Econometric Analysis of Merger Impacts, Application 88-12-035, July, 1990, Exhibit 10,511.

1989-1990: Working with Arthur D. Little, Inc., Dr. Hartman participated as a principal investigator and testifying expert in a merger study for several small New England utilities within Nepool. Dr. Hartman designed and implemented a statistical study of returns to scale and scope in the industry. Using the statistical results, Dr. Hartman developed opinions regarding the efficiency effects of the proposed merger. His analysis appears as an independent Appendix to

Arthur D. Little, Inc., Evaluation of EUA's Proposed Acquisitions of UNITIL and Fitchburg, Report to Gaston and Snow, March 12, 1990, presented in support of the acquisition to the Securities and Exchange Commission and the New Hampshire Public Utilities Commission.

1990: Working for a group of commodity futures exchanges, Dr. Hartman participated as Principal Investigator in a critical review of a statistical and econometric study performed by the Commodity Futures Trading Commission. The CFTC study was developed to assess the effects of dual trading on commodity futures markets, in order to implement proposed regulations curtailing such trading.

1990: Working with Barakat and Chamberlin, Inc., Dr. Hartman developed a Ramsey pricing model for Arizona Public Service Corporation. The Ramsey pricing model was used to develop and explore alternative rate strategies for a variety of residential, commercial and industrial market segments. The analysis was submitted in formal rate hearings.

1990-1992: Working with the Technology Research Center of Arthur D. Little, Inc. for the United States Postal Service, Dr. Hartman specified and estimated econometric models to analyze the determinants of productivity for the largest 120 post offices in the United States. The econometric models are being used to identify the most and least productive offices, with the purpose of learning from the performance of the most productive offices in order to improve the performance of the least productive offices. The models are being used to design and implement incentive regulation mechanisms to increase productivity across post offices.

A second set of econometric models have been specified and estimated to quantify the effects of the attributes of alternative postal services and rate classes upon total postal service costs. The results of this analysis are being used to design postal rates for alternative classes of service which reflect the real costs of providing the services. The analysis and its results will be introduced into the postal rate hearings.

1990-1997: Working with the World Bank, Dr. Hartman has specified and is estimating a set of econometric models to measure both the level and types of pollutants emitted by United States plants and establishments and the costs of abating those pollutants. The models identify and quantify, at the plant level, the relationship between the emission of approximately 300 pollutants and the scale of production, the types of technology used, the age and characteristics of the plant and equipment used, the extent to which abatement equipment has been installed, and the costs (capital and operating) of abating alternative pollutants.

The models will be used in the following ways in developing countries and Eastern European countries: to assist the countries to predict and assess the environmental implications of reliance upon certain technologies and industries in development; to assess the effectiveness of alternative regulatory methods for abating pollution, including effluent standards, effluent taxes, effluent licenses, technology standards, effluent banks, and alternative property right schemes; to implement incentive regulation mechanisms to better stimulate abatement compliance; and to identify and prioritize those industries that can abate certain pollutants at least cost.

As part of this effort, Dr. Hartman has also designed a specific incentive regulation system for pollution abatement compliance in Indonesia. The system is based upon the most recent theory in regulated incentive mechanisms. The system will ultimately evolve into an effluent bank or a system of effluent fees. If the effort is

successful, it will form the basis for environmental institutions in other developing countries. In the process of designing this system, he has reviewed the institutional and statutory basis for environmental policy in Indonesia.

Also as part of this work, Dr. Hartman is in the process of designing the institutional and statutory structures for Environmental Protection Agencies in a variety of developing countries. The institutional structures will be designed to articulate and implement pollution abatement policies that are informed by the econometric modeling described above.

1991: Dr. Hartman participated as a principal investigator and testifying expert for the Missouri Public Service Commission in a critical analysis of the proposed merger between Kansas Power and Light Company and Kansas Gas and Electric Company. Dr. Hartman's responsibilities included overall study design, analysis of scale and scope economies arising with the merger, analysis of unanticipated transitional cost arising with the merger and an econometric event study of the stock market's response to the merger. His testimony appears in

A Critical Analysis of the Proposed Merger Between Kansas Power and Light Company and Kansas and Electric Company, Report to the Missouri Public Service Commission, March 25, 1991.

1991: Working for the Resolution Trust Corporation in its litigation against Michael Milken and Drexel Burnham Lambert Inc., Dr. Hartman developed data and econometric models to measure the size of the relevant antitrust markets dominated by Drexel and to estimate the size of the economic damages produced by Drexel's alleged monopolization of those markets.

1991-1992: Working for the Indonesian government and the United States Agency for International Development, Dr. Hartman critically reviewed the structure of the Indonesian electric power industry and the institutions regulating that industry. The purpose of the analysis was to assist the government with privatizing their energy industries. His analysis focused upon the following: developing better data and models for predicting demand and supply; identifying and implementing more efficient industrial structures; and developing better regulatory regimes.

1992: Working for the World Bank, Dr. Hartman designed methods to measure and compare the social value of the environmental effects of alternative development projects, at the microeconomic and macroeconomic levels. His analysis focused upon standard and contingent valuation survey approaches and their use in econometric settings.

1992-1993: Working for the World Bank in Bangkok, Dr. Hartman characterized and critically analyzed the environmental effects of Thailand's energy use patterns. He focused upon the use and production of electric power, petroleum, coal and natural gas. He developed recommendations for environmental policy changes that included, but were not limited to, fuel taxes, effluent standards, technology standards, and privatization of environmental monitoring within a "bubble" policy approach.

1992-1993: Working for a biomedical company (a producer of vascular grafts) in an antitrust situation, Dr. Hartman designed and implemented survey techniques and econometric models to measure the size of the relevant markets and market power within those markets.

1992-1993: In a proceeding before the International Trade Commission, Dr. Hartman critiqued ITC econometric methods used for estimating elasticities of demand, supply and substitution among domestic and imported products. His focus was selected steel products. He formulated and estimated alternative models and methods to improve the existing estimates. He developed presentation materials for the Commission and testified before the Commission. His testimony is included in

LECG, Petitioners' Economic Testimony in the Matter of Certain Carbon Steel Flat Products, Final Hearing before the United States International Trade Commission, June 29-30, 1993; and

LECG, Petitioners' Post Hearing Brief in the Matter of Certain Carbon Steel Flat Products, before the United States International Trade Commission, July 7, 1993.

1992-1997: Working for the World Bank, Dr. Hartman has designed and is currently implementing a set of regional econometric/engineering models that accurately portray and predict the economic, environmental, infrastructural and socio-demographic effects of large-scale, World-Bank-funded infrastructural projects. The models combine input-output and econometric methods.

Given the Bank experience that many of their financially-sponsored projects create significant unanticipated environmental effects, the models are designed to be broad and comprehensive enough to incorporate and predict all important effects. The models systematically characterize the relationship between resource-based economic growth and the regional environment in which that growth occurs.

The models are currently being implemented for assessing project developments in the Carajas region of the Brazilian Amazonian rain forest, which is a large, dynamic and ecologically sensitive frontier area. The methods implemented for Brazil will be generalized for analysis of economic growth in ecologically similar areas, such as the Lake Baikal region of the former Soviet Union.

1993-1994: Working for the Commonwealth of the Northern Mariana Islands, Dr. Hartman developed and presented testimony rebutting a complaint by the United States Department of Justice that the Public School System of the Commonwealth practiced employment discrimination against teachers of Filipino and native Carolinian origin. Dr. Hartman's testimony examined both hiring and compensation practices. His testimony included hedonic regression analysis of the market for public school teachers in the islands. This analysis measured how teacher attributes and qualifications determined teacher salaries and hiring. The results of the analysis indicated that salary differentials resulted from differences in teacher qualifications rather than discrimination.

1993-Present: Working either as the testifying expert or supporting other testifying experts, Dr. Hartman has participated in a variety of patent infringement cases. He has developed, supported and estimated alternative theories and measures of damages for manufacturers of coaxial cable and a variety of alternative medical devices.

1993-1998: Working as the testifying expert, Dr. Hartman developed models estimating the damages to the business of a construction general contractor that were caused by the malicious prosecution of the contractor's insurance company.

1994: Working for the United States Wheat Associates in a proceeding before the ITC, Dr. Hartman designed and implemented an econometric study to assess and quantify the extent to which Canadian Wheat Board imports into the U.S. undersold domestic supplies and thereby materially interfered with the United States Department of Agriculture Wheat Program. The econometric study was hedonic. The study measured how non-price attributes are valued in U.S. wheat markets. The non-price attributes analyzed included such

things as protein content, shipment defects, moisture content and a number of end-use performance characteristics. Having measured the value of these attributes in U.S. markets, the analysis indicated how the Canadian Wheat Board fixed import prices below market levels, given the attributes of the imported wheat.

1994: Working as a testifying expert for Gallo Wines in a proceeding before the ITC, Dr. Hartman designed and implemented a statistical study of the US wine industry that analyzed the impacts of Chilean wine imports upon the domestic industry that would result from the inclusion of Chile in a Free Trade Agreement with the US.

1994: Working as a testifying expert for an insurer of a member of the Asbestos Claims Facility and Center for Claims Resolution, Dr. Hartman developed a statistical analysis estimating alternative indemnification liabilities expected under the Settlement Share Analysis of the Center for Claims Resolution and under the tort system. The results were used to make strategic decisions regarding the desirability of participating in the Class Action Settlement relative to litigating the claims.

1994: Working for several regional Bell Operating companies, Dr. Hartman has developed models and survey procedures to analyze and quantify the determinants of demand for local services, long-distance services and PCS services. The models quantify how consumers respond to and select among alternative carriers who differentiate their services by performance attributes and vendor reputation. The models also estimate the level of service demand, conditional upon the selection of service vendor. The models are being used to quantify the nature of competition among local carriers and long-distance carriers in the Intralata market. The models are also being used to help develop bidding strategies for specific RBOCs as they participate in the FCC auctions for the PCS spectra.

1995: Working as a testifying expert for a group of independent television stations and program producers, Dr. Hartman developed an econometric analysis of the impacts of the Prime Time Access Rule (PTAR) upon the economic performance of independent television stations. The analysis was submitted to the Federal Communications Commissions as part of their consideration of the repeal of the Rule. Dr. Hartman's analysis proved that PTAR had a strong, statistically significant effect upon the economic performance of these stations, and that its repeal would adversely impact them.

His testimony is included in

The Economic Effects of Repealing the Prime Time Access Rule: Impact on Broadcasting Markets and the Syndicated Program Market, Report prepared by LECG and presented before the Federal Communications Commission, MM Docket No. 94-123, March 7, 1995.

1995: Working for a big six accounting firm, Dr. Hartman designed and implemented a hedonic regression analysis to calculate transfer prices under the comparable uncontrolled price (CUP) method. The analysis is discussed in

"The Use of Regression Techniques in Transfer Price Analysis," with Delores Wright and J.D. Opdyke, European Taxation, 1996.

1995-1996: Working as the testifying expert for a major high tech firm in New England, Dr. Hartman has developed rebuttal and affirmative testimony to rebut claims of age discrimination in the termination of a group of employees over forty. His rebuttal testimony involved critically reviewing statistical analyses purporting to demonstrate disparate treatment and disparate impact. His affirmative testimony has involved designing and implementing econometric models to identify and estimate those factors actually determining the compensation and termination decisions of the defendant.

1995-1996: Working as the testifying expert for the Office of Attorney General of the State of Massachusetts, Dr. Hartman has analyzed and helped develop the State's positions on the following issues: restructuring the electric utility industry in Massachusetts and New England; regulating those entities in the restructured industry that will remain subject to regulation; and valuing those assets that may be stranded as a result of restructuring. As part of the effort, Dr. Hartman also critically reviewed the restructuring proposals of the largest utilities in the state. His testimony appears in

"The Market for Power in New England: The Competitive Implications of Restructuring," a report prepared for the Office of the Attorney General, Commonwealth of Massachusetts and submitted February 16, 1996 in support of their filing to the Department of Public Utilities as part of DPU 95-30, which was initiated August 15, 1995.

1995-1996: Working as the testifying expert, Dr. Hartman represented Florida Power Corporation in a contract dispute with Independent Power Producers. His analysis and testimony focused upon issues of damages incurred as a result of a breach of contract.

1995-1999: Working with a team of economists, Dr. Hartman represented the group of wholesalers in the retail prescription drug price fixing conspiracy case. His efforts included industry analysis and participation in cross examination of plaintiffs' experts.

1996: Working as the testifying expert for the Division of Public Utilities of the State of Rhode Island, Dr. Hartman has analyzed and helped develop the State's positions on restructuring the electric utility industry in Rhode Island and New England, for both the State's Public Utilities Commission and the FERC. As part of the effort, Dr. Hartman also critically reviewed the restructuring proposals of some of the utilities in the state. His testimony appears in

"The Division Plan to Restructure the Electric Utility Industry in Rhode Island," Volume 2 of Supporting Testimony to the State of Rhode Island and Providence Plantations Public Utilities Commission, in re: Electric Industry Restructuring, Docket 2320, April 12, 1996.

1996: Working with a team of engineering firms, an international investment banking firm, a big six accounting firm and several national law firms, Dr. Hartman developed models of demand, supply and futures markets in restructured electric power markets to assist a major industry participant in evaluating specific alternative acquisition strategies.

1996: Working with a team of economists developing evidence for presentation before the High Court of New Zealand, Dr. Hartman critically reviewed and rebutted a variety of econometric analyses of natural gas markets and more broadly-defined energy markets in New Zealand. These analyses were used to determine the size of antitrust markets for a variety of energy products.

1996: Dr. Hartman was retained by a major mid-west utility to critically review and rebut analyses and evidence presented before the FERC and the relevant State Commissions concerning the competitive impacts of the proposed Primergy merger.

1996-2003: Working as the testifying expert, Dr. Hartman analyzed the employment practices and procedures of the Florida Power Corporation during a reduction in force, to assess the validity of a complaint that those practices and procedures resulted in a pattern of age discrimination. In his testimony, Dr. Hartman implemented a variety of statistical and econometric analyses to address and quantify claims of disparate impact and disparate treatment.

1996-1997: Working for US Airways with a team of economists, Dr. Hartman specified and estimated a variety of econometric consumer choice models to measure customer preferences for the services of alternative air carriers in a cross section of US-European origin-destination markets. The models were used to evaluate the economic impacts of both the proposed alliance between American Airlines and British Airways and alternative proposals to condition that alliance.

1996-1997: Working as the testifying expert, Dr. Hartman represented a major national retail pharmaceuticals wholesaler in litigation brought by a regional distributor alleging monopolization of wholesale services to distinct classes of trade. His analysis addressed market definition, the analysis of competition generally and analysis of the competitive impact of specific contractual arrangements.

1997: Working with a team of experts, Dr. Hartman analyzed economic impacts of the construction of the Warrior Run Cogeneration plant which was under construction in Western Maryland and was contracted to sell power to Allegheny Power System's (APS) Maryland subsidiary, Potomac Edison.

1997: Working as the testifying expert for the Office of Ratepayer Advocates of the California Public Utilities Commission, Dr. Hartman critically reviewed the efficiencies estimated by Applicants to be induced by the proposed merger of Pacific Enterprises and Enova Corporation.

1997: Working with a team of economists, Dr. Hartman prepared affirmative and rebuttal testimony in a breach of contract matter in the pharmaceutical industry arbitrated before the International Chamber of Commerce.

1997-2000: Working as the testifying expert, Dr. Hartman developed analysis supporting certification of class and estimation of damages for the class of purchasers of thermal fax paper in the US over the period 1990-1992 who were damaged as a result of a price fixing conspiracy by major suppliers.

1998: Working as the testifying expert, Dr. Hartman analyzed the employment practices, procedures and personnel data of the Florida Power Corporation, in general and in particular, to assess the validity of a complaint that a specific employee had been subjected to racial discrimination.

1998-1999: Working with a team of economists for the Office of the Attorney General of the State of Massachusetts, Dr. Hartman developed and implemented econometric models to analyze and measure the health care costs arising under the Medicaid program that have been attributable to smoking. The analysis appears in the following documents:

David M. Cutler, Arnold M. Epstein, Richard G. Frank, Raymond S. Hartman, Charles King and Joseph P. Newhouse, *The Impact of Smoking on Medicaid Spending in Massachusetts: 1970-1998 -- Report on Methods*, June 15, 1998;

David M. Cutler, et. al., *The Impact of Smoking on Medicaid Spending in Massachusetts: 1970-1998 - Results From The Inclusive Approach for Adults*, July 1, 1998;

David M. Cutler, et. al., *The Impact of Smoking on Medicaid Spending in Massachusetts: 1991-1998 - Results From The Disease-Specific Approach for Adults and Overall Summary*, July 11, 1998.

Drawing upon these efforts, Dr. Hartman worked with the same team of experts to analyze the economic impacts of the Master Settlement Agreement and to present their findings to the Tobacco Fee Arbitration Panel.

1999: Working as one of two testifying experts for the Office of the Attorney General of the Commonwealth of Massachusetts, Dr. Hartman critically analyzed potential rate increases relevant to Joint Petitions introduced by both Eastern Enterprises/Colonial Gas Company and Boston Edison/Commonwealth Energy Systems. His testimony appears as

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of the Massachusetts Attorney General, in the matter of the Joint Petition of Eastern Enterprises and Colonial Gas Company For Approvals of Merger Pursuant to G.L. c. 164, §§ 96 and 94, DTE 98-128, March 26, 1999.

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of the Massachusetts Attorney General, in the matter of the Joint Petition of Boston Edison Company, Cambridge Electric Light Company, Commonwealth Electric Company and Commonwealth Gas Company For Approval of Rate Plan Pursuant to G.L. c. 164, §§ 76 and 94, DTE 99-19, April 30, 1999.

1999-2000: Dr. Hartman was retained by a group of industrial purchasers of copper to develop and implement methods and models to assess liability and measure damages in the matter involving the manipulation of the spot and future prices of copper on the London Metals Exchange by Sumitomo Corporation and Yasuo Hamanaka over the period 1987-1996.

1999-Present: Dr. Hartman consulted with counsel and the testifying expert in the development of data and models needed to certify class and measure damages in a price fixing case involving the manufacturer (Mylan) of generic clorazepate and lorazepam.

1999-2001: Working as the testifying expert, Dr. Hartman analyzed liability arising from a variety of restrictive dealer arrangements implemented by Dentsply International Inc., a U.S. manufacturer of artificial teeth, to foreclose entry by rival manufacturers from the US dental-laboratory dealer network. Dr. Hartman developed and implemented methods to measure damages to the class of dental laboratories that purchased artificial teeth from Dentsply at prices above the competitive prices that would have obtained absent the restrictive dealer arrangements.

1999-2000: Working with a team of economists for the Federal Trade Commission, Dr. Hartman analyzed the pro-competitive and anti-competitive nature of settlement agreements between generic and pioneer drug manufacturers resolving patent infringement litigation arising from certification under Paragraph IV of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act). Particular settlements analyzed include the settlement between Abbott Laboratories and Geneva Pharmaceuticals regarding the drug Hytrin and the settlement between Hoechst Marion Roussel (Aventis) and Andrx Corporation regarding the drug Cardizem.

1999-2000: Working as the testifying expert for the class of purchasers of Nine West shoes, Dr. Hartman was asked to analyze liability and measure damages arising from an alleged conspiracy to raise and maintain the prices of women's shoes manufactured by the Nine West Group Inc. and sold by a variety of general merchandise retailers through their upscale retail department stores. The defendants in the case included Nine West Group Inc., Federated Department Stores, Inc., Dayton Hudson Corporation, Lord and Taylor, Nordstrom, Inc., May Department Stores, Macy's, Bloomingdale's, Inc., and other general merchandise retailers.

2000: Working with the testifying expert, Dr. Hartman assisted in the analysis and estimation of economic damages to a Class defined as all smokers with 20-pack years each of whom contracted lung cancer which was substantially contributed to by cigarette smoking.

2000: Working with a team of economists, Dr. Hartman developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of structural steel beams during the period 1998-1999. The work was presented before the International Trade Commission.

2001: Working with a team of economists, Dr. Hartman developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of structural steel beams and during 2000. He also developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of cold rolled and hot rolled steel during the Period of Inquiry of 1997-1999. Both efforts were presented before the International Trade Commission.

2001-present : Working as the testifying expert, Dr. Hartman developed and submitted testimony in support of class certification of and the calculation of damages to the class of indirect purchasers of the anti-hypertensive drug, Hytrin, produced by Abbott Laboratories and the generic equivalent of Hytrin, generic terazosin hydrochloride, produced by Geneva Pharmaceuticals. The class alleges monopolization and violation of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act).

2001-Present: Working as consultant and testifying expert, Dr. Hartman has been retained by counsel to the classes of indirect or direct purchasers of a variety of branded pharmaceuticals (including but not limited to Augmentin, Bextra, Cipro (New York, California, U.S.), BuSpar, Celebrex, Vioxx, K-Dur, Taxol, Lupron, Relafen, Paxil, Remeron, Tamoxifen, Premarin and Wellbutrin) to analyze and submit testimony dealing with class certification, liability, market definition, damage calculations and settlement allocations arising from violations of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act) and related state-specific unfair competition statutes.

Dr. Hartman's testimony in this area has been relied upon (and cited thereto) for certification of end-payer consumer classes in the following matters:

- *In re: Terazosin Hydrochloride Antitrust Litigation*, United States District Court, Southern District of Florida, Case No. 99-MDL-1317-Seitz/Klein [Order Granting Indirect Purchaser Plaintiffs' Motions for Class Certification of State-Wide Classes, April 8, 2004]

- *In re Cipro Cases I and II*, D043543 (JCCP Nos. 4154, 4220), Court of Appeal, Fourth Appellate District, Division One, State of California [Decision affirming class certification not titled but marked as "Not to Be Published in Official Reports," Filed 7/21/04]
- *In re: Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-12239-WGY [Memorandum granting certification for an exemplar class, May 12, 2004]

Dr. Hartman's testimony has been relied upon (and cited as necessary) for approval of proposed settlement allocations in the following matters:

- *In re: Lupron® Marketing and Sales Practices Litigation*, United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS [Memorandum and Order Approving Settlement and Certifying the Class, May 12, 2005]
- *HIP Health Plan of Florida, Inc., On Behalf of Itself and All Others Similarly Situated v. Bristol-Myers Squibb Co. and American Bioscience*, Case Number 1:01CV01295, United States District Court for the District of Columbia
- *In re Buspirone Antitrust Litigation*, MDL No. 1413, United States District Court for the Southern District of New York
- *In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY
- *In re Remeron Antitrust Litigation*, United States District Court, District of New Jersey, Master Docket No. 02-CV-2007

2001: Working as consultant to counsel for various U.S. steel producers, Dr. Hartman worked with a team of economists to develop econometric models to analyze and measure the impacts of imports, demand and factor price changes upon the prices of domestically produced carbon steel flat products and carbon steel long products in the Section 201 hearings before the International Trade Commission. Dr. Hartman testified before the ITC in the hearings. The Commission decided in favor of most of the products subject to these analyses.

2001: Working as consultant to counsel for Nucor Steel Corporation, Dr. Hartman worked with a team of economists to develop econometric models to analyze and measure the impacts of imports, demand and factor price changes upon the prices of domestically produced carbon steel cold rolled products for preliminary hearings before the International Trade Commission.

2001-2002: Consulting to counsel for the Plaintiff Class, Dr. Hartman analyzed the targeting of youth by cigarette advertisements in the matter *in re Devin Daniels, et. al., v. Philip Morris Companies, Inc., et. al.*, Case Number 719446, coordinated with JCCP 4042.

2001-2003: Working as testifying expert, Dr. Hartman developed and presented statistical evidence analyzing the relative performance of a particular cardiovascular surgeon litigating the fact that his surgical privileges had been revoked as a result of incompetent surgical performance and results. He testified before an arbitration panel in the matter.

2003: Working as the testifying expert for Defendants, Dr. Hartman submitted testimony analyzing the allegation of racial discrimination on the part of Wells Fargo Home Mortgage, Inc. and Norwest Mortgage, Inc.

2003: Working as a consulting expert to counsel for the class of purchasers of graphite electrodes, Dr. Hartman developed econometric models to assess the impact of alleged antitrust violations.

2003: Working as a consulting expert for counsel to the class of direct purchasers, Dr. Hartman reviewed materials in a matter regarding antitrust allegations concerning the manufacture and sale of microcrystalline cellulose in the United States.

2003: Working as a consulting expert to counsel for a large electrical generation company, Dr. Hartman developed economic and econometric models to analyze the allegation that this electrical generation company participated in a conspiracy to manipulate prices of power sold in California.

2003: Working as the testifying expert, Dr. Hartman submitted testimony which analyzed and calculated the economic impacts and damages to the U.S. growers and quota holders of flue-cured and burley tobacco leaf caused by a price-fixing conspiracy among the major U.S. tobacco leaf buyers and cigarette manufacturers.

2004: Working as the consulting expert for the United States Department of Justice, Dr. Hartman critically analyzed the calculation of the economic damages borne by an electric power generation utility as a result of the breach of the Standard Contract with the U.S. Department of Energy to remove spent nuclear fuel in 1998. Dr. Hartman's analysis included a critical review and rebuttal of the models and data put forward by the utility's experts in the calculation of damages; the development and presentation of alternative and improved models and corrected data to more accurately calculate damages; a critical review of econometric analyses put forward by one of the utility's experts; and a review of the economics of re-licensing existing nuclear generating facilities.

2004: Working as the testifying expert, Dr. Hartman submitted testimony in support of the certification of the class of purchasers of electrical carbon products who have been alleged to have been impacted and injured economically as a result of a price-fixing customer-allocation conspiracy of the major suppliers of such products in the United States.

2004-Present: Working as the testifying expert, Dr. Hartman submitted testimony in support of the certification of the class of end payer purchasers of those pharmaceutical products produced by AstraZeneca, the Bristol Myers Squibb Group, the Johnson and Johnson Group, the Glaxo-Smith-Kline Group and the Schering Plough Group that were subject to an alleged scheme to fraudulently inflate their Average Wholesale Price (AWP), thereby fraudulently inflating the reimbursement rates paid by the Class members for those pharmaceuticals when their reimbursement rates were formulaically related to the AWP. Dr. Hartman is consulting on related litigation undertaken by the Offices of the Attorneys General for the States of New York, Connecticut, Arizona, Nevada, Montana Massachusetts and Pennsylvania. He has also submitted testimony establishing liability and calculating damages for those Classes certified by the MDL Court and those States seeking remedy.

2004-2005: Working as a consulting expert to counsel for a major electricity and gas utility holding company, Dr. Hartman developed models to evaluate allegations of affiliate abuse by the regulated gas distribution entities and the trading entities of the holding company. The alleged abuses concerned spot and forward gas markets in California.

2005: Working as the testifying expert for the United States Department of Justice, Dr. Hartman developed models to critically analyze the cost submissions to the U.S. Court of Federal Claims by the TVA for monetary damages alleged to have resulted from partial breach by the U.S. Department of Energy of the Standard Contract to remove spent nuclear fuel from TVA beginning in 2002. Dr. Hartman's analysis included a critical review and rebuttal of the models, data and cost analyses put forward by the utility and the development and implementation of alternative and improved models and corrected data to more accurately calculate costs attributable to the alleged partial breach.

2005-2006: Working again as the testifying expert for the United States Department of Justice, Dr. Hartman developed models to critically analyze the cost submissions to the U.S. Court of Federal Claims by the Systems Fuel Inc. (a subsidiary of Entergy) and Entergy for monetary damages alleged to have resulted from partial breach by the U.S. Department of Energy of the Standard Contract to remove spent nuclear fuel from Entergy facilities in Mississippi and Arkansas. Dr. Hartman's analysis has included a critical review and rebuttal of the Entergy's models, data and cost analyses put forward by the utilities and the development and implementation of alternative and improved models and corrected data to more accurately calculate costs attributable to the alleged partial breach.

2006: Working as the testifying expert for counsel to the Plaintiffs in the matters *In Re: Prempro Products Liability Litigation* (in the United States District Court for the Eastern District of Arkansas, Western Division, MDL #1507, July 31, 2003) and *In Re: Hormone Therapy Litigation* (in the Court of Common Pleas Philadelphia County, MDL #00001, November 2003), Dr. Hartman analyzed and measured the importance of the Premarin family of products to its manufacturer, Wyeth Corporation, in terms of sales, profitability and market strategies since the introduction of Premarin in the United States in 1943. He analyzed and calculated compensatory damages in the form of unjust enrichment earned by Wyeth as a result of the sale of the Premarin family of products over the period 1990-2002. He also developed methods for determining the amount of punitive damages relevant to the allegations in these matters.

2006: Working as the testifying expert for counsel to a class of end-payors, Dr. Hartman analyzed whether that class was impacted, injured and damaged economically as a result of a scheme involving Defendants McKesson Corporation and First DataBank (FDB), a scheme alleged to inflate the mark-up between two pharmaceutical list prices (the wholesale acquisition cost (WAC) and the average wholesale price (AWP)). The impact of the "AWP Inflation Scheme" was to fraudulently increase the reimbursement rates paid by the class members, since those reimbursement rates were and are formulaically determined by the inflated AWP. As part of his analysis, Dr. Hartman submitted additional testimony calculating consumer benefits arising from a proposed settlement between Defendants and Court to eliminate the "AWP Inflation Scheme." The settlement is described in *Settlement Agreement and Release, New England Carpenters Health Benefits Fund, et al. v. First Databank, Inc., and McKesson Corporation*, United States District Court District of Massachusetts, C.A. No. 1:05-CV-11148-PBS, August 2006.

**RECENT TESTIMONY OF RAYMOND HARTMAN  
AT DEPOSITION, HEARING OR TRIAL**

**1995**

*The Economic Effects of Repealing the Prime Time Access Rule: Impact on Broadcasting Markets and the Syndicated Program Market*, report presented in informal hearings before the Federal Communications Commission, MM Docket No. 94-123, March 7, 1995

*Gillam v. Abex, et. al.*, San Francisco Superior Court No. 966241, 1995 (deposition)

*Trilogy Communications Inc. v. Times Fiber Communications & LPL Technologies Inc.*, United States District Court for the Southern District of Mississippi, Jackson Division, Civil Action No. J91-0542 (W)(S), 1995 (deposition)

**1996**

*Hall v. Abex, et. al.*, San Francisco Superior Court No. 958853, 1996 (deposition)

*Sowers v. Abex, et. al.*, San Francisco Superior Court No. 949184, 1996 (deposition)

**1997**

*Hillenbrand v. INA/Aetna*, Sacramento County Superior Court No. 519223, 1997 (deposition)

**1998**

*Hillenbrand v. INA/Aetna*, Sacramento County Superior Court No. 519223, 1998 (trial)

*Trilogy Communications Inc. v. Pennie & Edmonds, LLP, et. al.*, United States District Court for the Southern District of Mississippi, Jackson Division, Civil Action No. CIV-3:97CV722BN (deposition)

*Paper Systems Incorporated v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd.* (Civil Action No. 96-C-959), consolidated with *Graphic Controls Corp. v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Appleton Papers, Inc.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd.* (Civil Action No. 97-C-412) and *Victor Paper Roll Products, Inc. v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Appleton Papers, Inc.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd.* (Civil Action No. 97-C-508), United States District Court for the Eastern District of Wisconsin (deposition)

**1999**

*Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of The Massachusetts Attorney General in. re The Joint Petition of Eastern Enterprises and Colonial Gas Company for Approvals of Merger Pursuant to G.L.c. 164 "96 and 94, before the Department of Telecommunications and Energy, D.T.E. 98-128 (hearing)*

*Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of The Massachusetts Attorney General in re The Joint Petition of Boston Edison Company, Cambridge Electric Light Company, Commonwealth Electric Company, and Commonwealth Gas Company for Approval of Rate Plan Pursuant to G.L.c. 164 " 76 and 94, before the Department of Telecommunications and Energy, D.T.E. 99-19 (hearing)*

**2001**

Oral testimony before the International Trade Commission regarding the impacts of imports, domestic demand and factor price changes upon the prices of domestically produced carbon steel flat products and carbon steel long products during the Section 201 Hearings (Inv. No. TA-201-073 (final))

**2002**

*In re Terazosin Hydrochloride Antitrust Litigation*, Case No. 99-MDL-1317 Seitz/Garber, consolidated, United States District Court for the Southern District of Florida, (deposition on affirmative and rebuttal testimony in support of class certification and deposition on affirmative testimony on damage analysis)

*In re Buspirone Antitrust Litigation*, United States District Court, Southern District of New York, MDL Docket No. 1410 (deposition on affirmative and rebuttal testimony on class certification)

*Anne Cunningham and Norman Mermelstein, Individually and on Behalf of all Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc, The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc.*, Index No. 603820-00, Supreme Court of the State of New York, County of New York (deposition on affirmative testimony on class certification)

*In re Ciprofloxacin Hydrochloride Antitrust Litigation*, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York. (deposition on affirmative testimony on class certification)

**2003**

*In re Terazosin Hydrochloride Antitrust Litigation*, Case No. 99-MDL-1317 Seitz/Garber, consolidated, United States District Court for the Southern District of Florida, (deposition on rebuttal testimony on damage analysis)

*Anne Cunningham and Norman Mermelstein, Individually and on Behalf of all Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc, The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc.*, Index No. 603820-00, Supreme Court of the State of New York, County of New York (deposition on rebuttal testimony in support of class certification)

*In re Ciprofloxacin Hydrochloride Antitrust Litigation*, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York. (deposition on rebuttal testimony in support of class certification)

*Cipro Cases I and II*, Judicial Council Coordination Proceeding Nos. 4154 and 4220 (Superior Court, San Diego County) (depositions on affirmative and rebuttal testimony in support of class certification)

*In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY (depositions on affirmative and rebuttal testimony on class certification and affirmative testimony on damages)

*Dr. Gregory Derderian, et. al., Plaintiffs, v Genesys Health Care Systems, et. al., Defendants, Case No. 99-64922-CK, State of Michigan, Circuit Court for the County of Genesee (testimony before arbitration panel)*

*In re S&M Farm Supply, Inc. v. Pharmacia Corporation; and Monsanto Company, Case No. 4:02CV518ERW, United District Court for the Eastern District of Missouri (deposition on affirmative testimony in support of class certification)*

*In re D. Lamar DeLoach, et. al., Plaintiffs, v. Philip Morris Companies, Inc., et. al., Defendants, in the United States District Court for the Middle District of North Carolina, Greensboro Division, Case No. 00-CV-1235 (depositions on affirmative and rebuttal testimony calculating damages)*

## **2004**

*In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York (depositions on affirmative and rebuttal testimony calculating damages and affirmative and rebuttal testimony analyzing liability and market definition)*

*In re Lupron Marketing and Sales Practices Litigation, MDL No. 1430, CA No. 01-CV-10861, United States District Court, District of Massachusetts (deposition on affirmative testimony in support of class certification)*

*In re Pharmaceutical Industry Average Wholesale Price Litigation, United States District Court for the District of Massachusetts, MDL, No. 1456, CIVIL ACTION: 01-CV-12257-PBS (deposition on affirmative testimony in support of class certification)*

## **2005**

*In re Lupron Marketing and Sales Practices Litigation, MDL No. 1430, CA No. 01-CV-10861, United States District Court, District of Massachusetts, (submission of written testimony at trial)*

*In re Tennessee Valley Authority, Plaintiff v. United States, Defendant, United States Court of Federal Claims, No. 01-249-C, (June 2, 2004 deposition and July 14-15, 2004 trial)*

*Lynne A. Carnegie v. Household International, Inc., Household Bank, f.s.b., successor in interest to Beneficial National Bank, Household Tax Masters Inc., formerly known as Beneficial Tax Masters, Inc., Beneficial Franchise Company, Inc., H&R Block, Inc., H&R Block Services, Inc., H&R Block Tax Services, Inc., H&R Block Eastern Tax Services, Inc., Block Financial Corp. and HRB Royalty, Inc., No. 98 C 2178, United States District Court for the Northern District of Illinois Eastern Division, (submission of written testimony and deposition in calculation of damages)*

## **2006**

*In re Pharmaceutical Industry Average Wholesale Price Litigation, United States District Court for the District of Massachusetts, MDL, No. 1456, CIVIL ACTION: 01-CV-12257-PBS (deposition testimony in calculation of damages for the State of Connecticut; submission of written testimony and deposition testimony in the calculation of damages and penalties for the State of Montana and the State of Nevada; submission of written testimony on summary judgment; submission of written testimony in support of class certification for Track 2 defendants)*

*System Fuels, Inc., on its own behalf and as agent for System Energy Resources, Inc. and South Mississippi Electric Power Association, Plaintiff, v. The United States, Defendant, in the United States Court of Federal Claims, No. 03-2624C (submission of expert report and July 25, 2006 deposition)*

*New England Carpenters Health Benefits Fund; Pirelli Armstrong Retiree Medical Benefits Trust; Teamsters Health & Welfare Fund of Philadelphia and Vicinity; and Philadelphia Federation of Teachers Health and Welfare Fund v. First Databank, Inc., and McKesson Corporation, United States District Court District of Massachusetts, C.A. No. 1:05-CV-11148-PBS (submission of written testimony in support of class certification)*

**Attachment B: Documents Relied Upon**

### **Attachment B: Documents Relied Upon**

#### **Bates-Numbered Documents:**

- AET 004285-86
- AZ 0233062-106
- AZ 0492927
- AZ0004662-84
- AZ0004734-55
- AZ0022281-94
- AZ0092152-62
- BMS/AWP/000071159-62
- BMS/AWP/0011247-8
- BMS/AWP/00986726
- BMS/AWP/01109782
- ESI-277-00002066-77
- FCC 000299
- FCC 000495
- FCC 000613
- FDB-AWP 15102-4
- FDB-AWP 02023
- GSK-MDL-KY01-007599
- GSK-MDL-KY01-008042-59
- GSKMDLKYTR02-0043706-7
- GSK-MDL-ZN-01-048606-9
- GSK-MDL-ZN02-072192
- HUM00839 – HUM00912
- HUM01151 – HUM01214
- HUM01867 – HUM01921
- KC0003265 – KC0003266
- SPH 002025
- TCC 000267
- TCC 000356-361
- TCC 000369
- TCC 000474
- TCC 001000

#### **Manufacturer Data:**

- AZ0466413-4
- AZ0682114
- AZ0687892-3

- BMS/AWP/001483004-14
- BMS/AWP/001491893
- BMS/AWP/00258327
- BMS/AWP/00258331
- MDL-CEN000103691
- MDL-HCS00013630-38
- MDL-HCS00275969-71
- MDL-HCS00275988
- MDL-HCS00282702
- MDL-OBI00056539
- MDL-PSGA00000001-2
- SPW0032447-8
- SPW0033547

**Claims Data:**

- Blue Cross Blue Shield of Kansas City Data: as Provided by Dr. Gaier
- Blue Cross Blue Shield of Massachusetts

**Depositions In re Pharmaceutical Industry Average Wholesale Price Litigation:**

Beaderstadt, Mike, September 17, 2004  
Bowman, Waldo, October 13, 2005  
Brennan, David R., February 14, 2006  
Brown, Mickey, March 9, 2005  
Chen, Thomas, December 14, 2005  
Cook, Jan, March 6, 2006  
Ellston, Kelly, November 23, 2004  
Farias, Robert C., October 20, 2004  
Fox, Steven, March 8, 2006  
Killian  
Edward Lemke, January 12, 2005  
Marre, Christof A., August 26, 2005  
Mulrey, Michael T., January 5, 2006  
Patterson, Keith, June 28, 2005  
Pfankuch, Paula, September 14, 2004  
Spahn, Joe, November 30, 2004  
Strand, Steven, June 17, 2005  
Thomas, David, September 24, 2004  
White, Halbert L., November 29, 2004  
Young, Steven J., November 18-19, 2004

**Plaintiffs' Exhibits:** 1, 3, 5, 14, 15, 69, 132, 133, 178, 184, 221, 222, 255, 256, 260, 268, 327, 334, 365, 394, 422, 982U

**Legal Documents:**

Berndt, Ernst R., Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, February 9, 2005.

Memorandum and Order re: Motion for Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257.

Sentencing Memorandum of the United States, United States of America v. TAP Pharmaceutical Products, Inc., United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY.

**Other Documents Relied Upon:**

*1991 Drug Topics Red Book*, Medical Economics Company Inc., 1991.

42 CFR 405.517, Revised October 1, 1996 and October 1, 2003.

Alpert, Bill, "Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?" *Barron's*, June 10, 1996.

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**Attachment C: Resource-Based Relative-Value Scales (RBRVS)**

## Attachment C: Medicare's Resource Based Relative Value Scale

### C.1 Rationale for the CMS RBRVS

1. Physicians and TPPs both benefit from having a relative value scale (RVS) that can be used as a basis of payment negotiations. HCFA, in cooperation with representatives of the American Medical Association (AMA) and societies of specialty physician providers, sponsored research in the early 1990s to develop the Resource-Based Relative Value Scale (RBRVS) to pay physicians under Part B on the basis of the thousands of procedures they perform. CMS maintains the RBRVS (modifying it over time). CMS also changes payment levels by specifying "update" factors; for example, raising the payment level for the next year by 2.5% while maintaining the relative level of payments associated with various procedures.

2. CMS's reliance upon an RVS is driven by transaction costs. This is a version of the "importance of being unimportant" phenomenon introduced by Professor Berndt. Because it is too costly to monitor and negotiate prices item-by-item, CPT-by-CPT, both payors and providers look for an economical way to calculate reimbursements due physicians that meet the goals of payment system.

3. The RBRVS for physician services under Part B has the following property:  
 (1)  $V_i/V_j \approx C_i/C_j$ .  
 Specifically, the "value"  $V_i$  assigned to procedure i in relation to the value assigned to procedure j is approximately equal to the relative costs of the two procedures.

4. A good payment system based on RVS has two properties. First, it covers the costs of the contracting physicians and encourages them to participate in the "network;" specifically, some multiple "k" times the sum of all values provided,  $k\sum V_i$ , should = total cost =  $\Sigma C_i$ . Note that if each procedure is **valued at cost**,  $k = 1$ . Second, for the incentive properties of

the RVS payment system to be correct at the level of the individual procedure, the payment for the procedure  $kV_i$  conveys an appropriate positive margin over its cost,  $C_i$ . If (1) holds exactly (and marginal costs are constant) we can see that there will be exactly the same (percentage) margin for each procedure; that is,

$$(1a) \quad kV_i/C_i = kV_j/C_j = m_i = m_j = m.$$

5. The purpose of developing the RBRVS was to create a relative payment methodology that would eliminate margins that were “too big” for some procedures (mainly surgical) and improve the margins on other procedures (mainly the “evaluation and management” type) that were too small. Although the objective of the RBRVS was to better equalize the “margins” in Equation (1a) (i.e.,  $m_i = m_j = m$ ) for alternative services, various compromises with reality make that equality only approximate. However, physicians do make decisions about rates of surgery and other procedures that are influenced by incentives in the payment system, as reflected by  $m_i$  and  $m_j$ . In order for those incentives to be neutral across procedures, the margins should be equalized at  $m$ .<sup>1</sup>

6. Finally note that  $m$  can be considered **the yardstick** for the neutral margin across all provider procedures designated by CPT codes  $i$  and  $j$ .

## C.2 Relevance to Part B Drug Reimbursement

7. The AWP-based drug reimbursement system is analogous to the RBRVS for provider services. Specifically, the AWP-payment methodology can be considered a relative value scale. The relative values are determined by the AWPs and the level of reimbursement

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<sup>1</sup> For a recent discussion of the desirability of this property of the RVS, see Ginsburg, Paul B. and Joy M. Grossman, “When the Price Isn’t Right: How Inadvertent Payment Incentives Drive Medical Care”, *Health Affairs*, Jul-Dec 2005, 24, pp 376-384.

paid. As above, a relative value scale is useful if Equation (1) holds approximately across drugs, or, in the case of AWP if:

$$(2) \quad AWP_i/AWP_j \approx ASP_i/ASP_j.$$

8. As above, a payment system based on the AWP should have two properties.

First, it should allow for coverage of the costs of all pharmaceuticals reimbursed as part of the practice of all network physicians; specifically, some multiple “k” times the sum of all values (here AWPs) =  $k\sum_i AWP_i$  = total provider cost =  $\sum_i ASP_i$ . Note that if drug claims are reimbursed at provider acquisition cost,  $kAWP_i = ASP_i$ , and  $k = ASP_i/AWP_i$ . Note also that if the value of each drug is set equal cost,  $ASP$ ,  $k = 1$  for all  $i$  and  $j$ . This is certainly the desired result of the OIG Compliance Program Guidance introduced in ¶ 2 of my Declaration. Second, for the incentive properties of the RVS payment system to be correct, we expect at the level of a specific drug therapy, the payment for the value of drug therapy  $i$  ( $AWP_i$ ) conveys an appropriate positive margin over its cost,  $ASP_i$ . Again, if (2) holds exactly, we can see that there should be exactly the same (percentage) margin for each drug therapy  $i$  and  $j$ ; that is,

$$(2a) \quad AWP_i/ASP_i = AWP_j/ASP_j = m_i = m_j = m.$$

9. In the case of drug therapies, the purpose of the RVS is to insure a relative payment methodology that eliminates margins that are “too big” for some drugs and “too small” for others. As with provider services (Equation (1a)), physicians do make decisions about which drugs to prescribe based upon the incentives in the drug reimbursement system, as reflected by  $m_i$  and  $m_j$ .<sup>2</sup> In order for those decisions to be neutral across drug therapies, the margins have been designed by CMS to be equalized at  $m$ .

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<sup>2</sup> For a recent discussion of the how doctors respond to these margins in prescribing alternative drug therapies and regimens, Jacobson, Mireille, A. James O’Malley, Craig C. Earle, Juliana Pakes, Peter Gaccione, and Joseph P. Newhouse, “Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?” *Health Affairs*; Mar/Apr 2006; Vol. 25, No. 2, pp 437-443.

10. Note however that while HCFA and CMS have designed the RBRVS system so that  $m_i$  and  $m_j$  will be approximately equalized, in the context of drugs it is precisely these margins that have been manipulated by manufacturers as part of the AWP Inflation Scheme to move market share of drug i over drug j. The manipulation has occurred through the inflation of AWP and/or the concomitant reduction of ASP, everything else equal. Note further that based upon Medicare's RBRVS practices and procedures, TPPs expected or anticipated the following:

- Equations (2) and (2a) held.
- AWPs embodied the properties of a RVS; i.e., were characterized by Equations (2) and (2a).
- That a summary measure of spread, m, characterized the relationship between the relative value measure (AWP) and the resource costs (ASP).

11. Unless these conditions characterized TPP and provider expectations, neither party would agree to use AWP as a RVS. *It would be economically irrational for a TPP to agree to a formula for payment that arbitrarily created incentives for over and under use of drugs.*<sup>3</sup>

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<sup>3</sup> Research shows that differential margins on procedures and drugs affect physician behavior, *Ibid.* TPPs have a goal not only of enlisting physicians in networks, but inducing them to provide appropriate care. An RVS with relative values unrelated to costs would confer arbitrary undesirable incentives and undermine the economic value of the health insurance offered by the TPP.

**Attachment D: OIG/GAO Summaries**

## Attachment D.1 Through D.3: Review of OIG and Other Industry Reports

Report Author	Report Title	Report	Report Date	Spread	Methodology of Spread Calculation	Type of Drug(s)
<b>D.1 Brand and Generic Drugs Sold at Retail</b>						
OIG	Use of AWP in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program	OIG	October 1989	AWP and ASP	Obtained prices from drug wholesalers and compared to "national drug pricing authorities" including Medispan and the Blue Book. Average discount for singles and multi-source drugs was 15.5%.	Sample of fifty-five single and multi-source drugs purchased by pharmacies.
GAO	Prescription Drugs: Changes in Prices for Selected Drugs	GAO	August 1992	Dollar Based	Comparison of AWP and other prices to determine changes in prices in relation to industry CPIs	Generic and brand drugs sold at pharmacy
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs	A-06-96-00030	April 1997	AWP Based	Invoice price as a percentage below AWP	Medicaid-covered brands sold at pharmacies
OIG	Semiannual Report, April 1, 1987 - September 30, 1987	OIG (DHHS)	April-Sept 1987	AWP Based	Based on OIG Reports. EAC percentage discount for brand and generic drugs off of AWP	Medicaid-covered brands sold at pharmacies
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products	A-06-00-00023	August 2001	AWP Based	The discount below AWP at which pharmacies purchase brand-name drugs	Medicaid-covered brands sold at pharmacies
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products	A-06-01-00053	March 2002	AWP Based	The discount below AWP at which pharmacies purchase generic drugs	Medicaid-covered generics sold at pharmacies
OIG	Medicaid Pharmacy - Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products	A-06-02-00041	September 2002	AWP Based	The discount below AWP at which pharmacies purchase generic drugs	Medicaid-covered generics sold at pharmacies
George Reeb	Testimony of George Reeb	CMS	October 2002	AWP Based	The discount below AWP at which pharmacies purchase generic and brand drugs	Generic and brand drugs sold at pharmacy
OIG	Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products	A-06-97-00011	August 1997	AWP Based	The discount below AWP at which pharmacies purchase generic drugs	Medicaid-covered generics sold at pharmacies
CBO	Medicaid's Reimbursements to Pharmacies for Prescription Drugs	CBO	December 2004	Ratio(AWP)	The difference between what Medicaid pays a pharmacy and the cost of acquiring the drug from the manufacturer, divided by Medicaid's payment Percentage below AWP	Medicaid-covered generics and brands
George Reeb	Testimony of George Reeb	CMS	December 2004	AWP Based	Hearing discusses both: markup over the acquisition cost and the discount off of AWP.	Generic and brand drugs sold at pharmacy
Hearing	Medicaid and AWP Hearing: Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much	Federal Hearing	December 7, 2004	AWP and ASP	Hearing discusses both: markup over the acquisition cost and the discount off of AWP.	Medicaid-covered generics sold at pharmacies
<b>D.2 Albuterol Sulfate</b>						
OIG	Medicare Payments for Nebulizer Drugs	OEI-03-94-00390	February 1996	Dollar Based	Suggests that Medicare should use EAC for reimbursement of nebulizer drugs rather than AWP	Nebulizers (Albuterol Sulfate and others)
OIG	Suppliers' Acquisition Costs for Albuterol Sulfate	OEI-03-94-00393	June 1996	Dollar Based	Comparison of Medicare reimbursement amounts and estimated acquisition/supplier costs	Albuterol
OIG	A Comparison of Albuterol Sulfate Prices	OEI-03-94-00392	June 1996	Medicare Price (AWP) Based	Comparison of Medicare reimbursement amounts and estimated acquisition/supplier costs	Albuterol
OIG	Are Medicare Allowances for Albuterol Sulfate Reasonable?	OEI-03-97-00292	August 1998	ASP Based	Medicare allowed up to 333% more than acquisition costs for albuterol	Albuterol
OIG	Medicare Reimbursement of Albuterol	OEI-03-00-00311	June 2000	Medicare Price (AWP) Based	Difference between the prices, divided by the Medicare reimbursement price	Albuterol
OIG	Excessive Medicare Reimbursement for Albuterol	OEI-03-01-00410	March 2002	Medicare Price (AWP) Based	Calculated as the percentage below the Medicare Allowable Amount, or as a ratio vs. the VA price	Albuterol
Tom Gray	Construction A Head	Homecare	October 1, 2002	EAC, WAC, VA Based	Refers to a previously published OIG report. Ratio to the VA price. Medicare is more than 9x higher than the VA price and higher than EAC.	Albuterol and Ipratropium Bromide
OIG	Update: Excessive Medicare Reimbursement for Albuterol	OEI-03-03-00510	January 2004	Dollar Based	Prices are compared, but no percentages are calculated	Albuterol
<b>D.3 Medicare Part B and Physician Administered Drugs</b>						
OIG	Physicians' Costs for Chemotherapy Drugs	A-02-91-01049	November 1992	AWP Based	Expressed as the invoice costs' percentage below the AWP	Chemotherapy drugs
Bill Alpert	Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals	Barron's	June 1996	AWP Based	Comparison of AWP and wholesale prices of about 300 dose forms. Article highlights a select number of PA drugs.	PA Medicare Part B generic and single-source drugs
OIG	Excessive Medicare Payments for Prescription Drugs	OEI-03-97-00290	December 1997	ASP Based	Reported as the Medicare allowed amount as a percentage above the average acquisition cost	Twenty-two of the top thirty Medicare Part B drugs with the highest total Medicare payments in 1995
Rozek and Berkowitz	The Costs to the US Health Care System of Extending Marketing Exclusivity for Taxol	Journal of Research in Pharm Econ	1999	AWP Based	Calculated as the percentage ratio of manufacturer price over the AWP	Taxol and a few other cancer drugs
Robert Pear	Administration Plans Cuts in Some Drug Payments	The New York Times	August 6, 2000	EAC/ASP Based	Describes the markups received by doctors as a percentage over their cost (up to 700%). Cites a 1997 DHHS cost-based report	PA Medicare Part B oncology drugs. Report cited 1987 DHHS study of 22 drugs
DHHS	Letter from Nancy-Ann Min DeParle	DHHS (HCFA)	September 8, 2000	Dollar Based	DOJ-collected pricing data compared to AWPs in Redbook. Dollar spread reported for only one example.	Reference to about 400 NDCs of 49 Medicare covered drugs
OIG	Medicare Reimbursement of Prescription Drugs	OEI-03-00-00310	January 2001	Dollar Based	Comparison is within Medicare and to VA and Medicaid Reimbursement, not comparing to ASP	Twenty-four of the top thirty Medicare Part B drugs with the highest total Medicare payments in 1999

Direct Testimony of Raymond S. Hartman

## Attachment D.1 Through D.3: Review of OIG and Other Industry Reports

Report Author	Report Title		Report	Report Date	Spread	Type of Drug(s)
Methodology of Spread Calculation						
ASCO	Reform of the Medicare Payment Methods for Cancer Chemotherapy	ASCO	May 2001	AWP Based	Spreads calculated based on difference between wholesaler prices and AWP for Medicare reimbursement	Oncology drugs
GAO	Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost	GAO-01-1118	September 2001	AWP Based	The discount below AWP at which providers and physicians are acquiring the drugs	PA Medicare Part B drugs
MASPIRG	Health Care Reform - Prescription for Quality, Health Care - The AWP Litigation	MASSPIRG	December 20, 2001	AWP Based	Cites discounts off of AWP. This is a press release from the PAL, describing this AWP litigation and cites the complaint.	Refers generally to drugs in this litigation.
Spears and Pearlman	Using Litigation to Regulate Drug Prices: The Assault on AWP	<i>Washington Legal Foundation</i>	February 2002	AWP Based	Cites the Nov 1992 OIG report, which is AWP based	Chemotherapy drugs
Dawn M. Gericelli	AWP for Prescription Drugs: Is There a More Appropriate Pricing Mechanism	National Health Policy Forum Issue Brief	June 7, 2002	AWP Based	Based on GAO-01-1118. The discount below AWP at which providers and physicians are acquiring the drugs	PA Medicare Part B drugs
MedPAC	Report to Congress: Variation and Innovation in Medicare	MedPAC	June 2003	AWP Based	Reports provider costs as a percentage of AWP	Medicare and Medicaid drugs
Federal Register	Fed Reg 42 CFR 405 and 414	Fed Reg	August 20, 2003	AWP Based	Cites the Nov. 1992 OIG report, which is AWP based	Chemotherapy drugs
OIG	Medicare Reimbursement for Lupron	OEI-03-03-00250	January 2004	Dollar Based	Prices are compared, but no percentages are calculated	Lupron and Zoladex
GAO	Medicare Chemotherapy Payments: New Drug and Administration Fees are Closer to Providers' Costs	GAO-05-142R	December 2004	AWP Based	Spreads are calculated based on difference between oncologists' EAC and Medicare reimbursement	Chemotherapy drugs

**Attachment D.4: Summary of OIG and Other Available Reports for Medicare Part B and Physician Administered Drugs**

<u>Report</u>	<u>Type of Drug(s)</u>	<u>Spread Calculation and Range</u>	<u>Spreads Reported?</u>	<u>Single/Multi-Reported?</u>
<b>OIG, Physicians' Costs for Chemotherapy Drugs (A-02-91-01049), November 1992</b>				
13	Chemotherapy drugs	Spreads reported as the percentage below the AWP.	Yes	Yes
6	Single-source drugs	Reported single-source spreads at 20% (manufacturer price); or 12-18% (oncology wholesaler price)		
7	Multi-source drugs	Reported multi-source spreads at 20-83% (manufacturer price); or 9-83% (oncology wholesaler price)		

<b>Bill Alpert, Hooked On Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals? Barron's, June 1996</b>				
13	"Off Patent" Medicare Part B drugs	Spreads reported as the percentage of actual wholesale costs below AWP for off patent Part B drugs.	Yes	Yes
	Single-source drugs	Spreads for single source drugs (e.g. Taxol and Platinol) "still enjoying patent protection" are reported to be generally 10-20% below AWP.		
13	Multi-source drugs	Average reported spread for 13 "off patent" multi-source drugs at 81% based on 1995 data (range from 58% to 93%)		

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi-Reported?
<b>OIG, Excessive Medicare Payments for Prescription Drugs (OEI-03-97-00290), December 1997</b>				
22	Medicare Part B drugs	Percent savings if drugs were purchased at the ACTUAL average wholesale price.	No	No
11	Single-source drugs	Average reported savings for 11 single-source drugs at 22.5% in 1995 and at 19.5% in 1996. Excluding Novantrone from 1995 and Kytril and Zofran in 1995 and 1996, the savings ranged from 15%-24% in 1995 and 13%-21% in 1996. (Novantrone was an outlier at 52% in 1995.)		
9	Multi-source drugs	Average reported savings for 9 multi-source drugs at 69% in 1995 and 64% in 1996.		
2	Multi-brand drugs	Average reported savings for 2 multi-brand drugs was 46% in 1995 and 42% in 1996. This ranged from 17%-74% in 1995 and 13%-71% in 1996.		
Note: The OIG Report analyzes 22 drugs and states there 10 single-source, 9 multi-source and 3 multi-brand drugs. However, they did not identify how they classified each drug. Our analysis indicates that of these 22, 11 were single-source, 9 were multi-source and 2 were multi-brand.				
<b>Rozek and Berkowitz, The Costs to the US Health Care System of Extending Marketing Exclusivity for Taxol, Journal of Research in Pharmaceutical Economics, 1999</b>				
4	Multi-source BMS cancer drugs	Spreads reported as the "intermediary margin" or the manufacturer price as a percentage below the AWP.	Yes	Yes
4	Multi-source drugs	Average spread for 4 BMS multi-source cancer drugs at 45.5% for the generic sources and 22.6% for the BMS brand from 1991-1996 (Table 2).		
<b>Robert Pear, Administration Plans Cuts in Some Drug Payments, The New York Times, August 6, 2000</b>				
Medicare Part B drugs Includes a summary of the December 1997 OIG Report (see above for actual spreads) and a general description of spread levels. No specific drugs or J-codes are listed in this article.				

<u>Report</u>	<u>Type of Drug(s)</u>	<u>Spread Calculation and Range</u>	<u>Spreads Reported?</u>	<u>Single/Multi Reported?</u>
<b>DHHS, Letter from Nancy-Ann Min DeParle, September 8, 2000</b>				
	Medicare Part B	DOJ-collected pricing data compared to AWPs in Redbook. Dollar spread reported for only one example. Reference to about 400 NDCs of 49 Medicare covered drugs	No	No
<b>OIG, Medicare Reimbursement of Prescription Drugs (OEI-03-00-00310), January 2001</b>				
24	Medicare Part B drugs	<i>Percent savings if drugs were purchased at the catalog median price instead of the Medicare median.</i>	No	No
17	Single-source drugs	Average savings for 17 single-source drugs at 16.3% based on 1999 data. After excluding Anzemet/dolasetron mesylate (44.1%) and Kytril/granisetron HCl (25.5%) all other reported savings are less than 17%.		
7	Multi-source drugs	Average savings for 7 multi-source drugs at 51.4% based on 1999 data. After excluding Lupron (15.8%) all savings are greater than 24%. (Lupron was an outlier at 15.8%).		
<b>ASCO, Reform of the Medicare Payment Methods for Cancer Chemotherapy, May 2001</b>				
	Oncology drugs	<i>Considered spreads to be the difference between AWP and actual selling price. Cited OIG (Nov 1992) report.</i>	No	No

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
<b>GAO, Medicare: Payments for Covered Outpatient Drugs Exceed Providers Costs (GAO-01-1118), September 2001</b>				
25	Medicare Part B drugs	Average widely available discount from AWP reported for 25 Medicare-covered drugs. Six other drugs were considered but spreads were not reported.	Yes	No
16	Single-source drugs	Average spread for 16 single-source drugs equaled 22.1%. Excluding Anzemet, the spreads range from 12.8% to 29.3%. (Anzemet was an outlier at 65%).		
9	Multi-source drugs	Average spread for 9 multi-source drugs at 59.2%. Excluding Lupron and dexamethasone sodium phosphate the spreads ranges from 34.4% to 85.6%. (Lupron and dexamethasone sodium phosphate were outliers at 17.6% and 14%, respectively.)		
<b>MASSPIRG, Health Care Reform - Prescription for Quality Health Care - The AWP Litigation, December 20, 2001</b>				
<i>Drugs subject to the AWP litigation</i>		This PAL news release describes this litigation and references a range of discounts off AWP from 13-34% to 65-85%. No drug-specific spreads are reported in this news release.	Yes	No
<b>Washington Legal Foundation, Using Litigation to Regulate Drug Prices: The Assault on AWP, February 2002</b>				
<i>Chemotherapy drugs</i>		White paper by Ropes and Gray attorneys. Cites the Nov 1992 OIG report, which is AWP based	No	No
<b>AWP for Prescription Drugs: Is There a More Appropriate Pricing Mechanism, National Health Policy Forum Issue Brief, June 7, 2002</b>				
<i>PA Medicare Part B drugs</i>		Cites several OIG reports, but other than one illustrative example, does not list any specific drug prices. Refers to GAO-01-1118.	No	No
<b>MedPAC, Report to Congress: Variation and Innovation in Medicare, June 2003</b>				
<i>Medicare and Medicaid drugs</i>		Reports provider costs as a percentage of AWP	No	No

Report	Type of Drug(s)	Spread Calculation and Range	Spreads Reported?	Single/Multi Reported?
<i>Federal Register, Fed Reg 42 CFR 405 and 414, January 7, 2004</i>				
Medicare Part B drugs		Reports spreads from the September 2001 GAO report and the January 2001 OIG report (see above for descriptions of spreads reported), plus others.	Yes	Yes
20 Single-Source		Spreads are calculated based on previously reported values for 20 single source drugs with an average of 16% spread. (Kytril and Anzemet were outliers at 25% and 41%, respectively). Excluding Kytril and Anzemet all other spreads were less than 18% (8% to 17%).		
9 Multiple-Source		Spreads are calculated based on previously reported information on 9 multiple source drugs with an average of 54%. Other than dexamethosone sodium phosphate (9%) the generic spreads ranged from 24% to 84%.		
<i>OIG, Medicare Reimbursement for Lupron (OEI-03-03-00250), January 2004</i>				
		Prices are compared, but no percentages are calculated	No	No
<i>GAO, Medicare Payments to Oncologists (GAO-05-142R), December 1, 2004</i>				
16 Medicare Part B drugs		Spreads calculated as Payment-to-Cost ratios. Acquisition cost estimates were based on drug price data obtained from IMS. Payment-to-cost ratios for 16 drugs billed to Medicare by oncologists exceeded estimated costs by 22% in 2004. (This is a weighted average based on 2003 utilization.) This study was requested to "review the adequacy of Medicare payments for chemotherapy-related drugs and chemotherapy administration services..."	Yes	No
13 Single-source drugs		Weighted average payment-to-cost ratio for 13 single-source drugs calculated at 14.2%		
3 Multi-source drugs		Weighted average payment-to-cost ratio for 3 multi-source drugs calculated at 376.2%.		

**Attachment E: Claims Analysis for BCBS-MA**

**Attachment E: Analysis of Information Sharing Within BCBS/MA**

1. In this Attachment, I assess whether TPPs are able to share spread information internally. To do so, I examine data from a Class 3 member TPP, Blue Cross Blue Shield of Massachusetts (BCBS/MA), which had a staff model HMO that purchased physician-administered drugs at ASPs. BCBS/MA has also been the largest medical insurer in Massachusetts over the Class Period. I focus upon whether the purchases made by the staff model HMO of BSBC/MA informed BCBS/MA sufficiently so that it negotiated lower reimbursement rates with its network providers for the same drugs, given that they had internal ASP information for those drugs.

2. If TPPs could benefit from and act upon knowledge concerning the “mega-spreads” that existed between the AWPs and acquisition costs of drugs (spreads which Defendants argue were fully understood and discounted by the market), one would certainly assume that large profit-maximizing TPPs would most likely be the entities that effectively make use of that information. Certain TPPs purchase directly the same physician-administered drugs for their staff model HMOs that they pay reimbursement claims to their network providers. One would expect that large profit-maximizing entities that purchase physician-administered drugs would be well informed and sufficiently economically agile to exploit such information and negotiate reimbursement rates to ASPs (rather than off AWP) with their network providers.

3. Blue Cross Blue Shield of Massachusetts (BCBS/MA) is a managed care organization with a variety of corporate divisions. One division is the medical insurance division, which offers standard medical insurance and reimbursed for medical claims submitted by network providers for the lives it insures. Another BCBS/MA division has provided healthcare services through a staff model HMO.

4. In order to analyze the extent to which intra-institutional exchange of information has provided BCBS/MA with better spread expectations to more aggressively negotiate discounts with providers, I have gathered and analyzed drug acquisition cost data for BCBS/MA, which purchased physician-administered drugs directly through contracts with manufacturers, through group purchasing organizations ('GPOs'), or through drug wholesalers for its staff model HMO business. Clearly, such purchases informed the BCBS/MA HMO of ASPs of physician-administered drugs. The data demonstrate that plaintiff BCBS/MA, the largest TPP in Massachusetts, purchased physician-administered drugs at substantial discounts from AWP and knew the magnitude of those discounts (*i.e.*, the magnitude of the spreads) since at least 1991.

5. Was that information communicated to the insurance side of BCBS/MA and did it change expectations and negotiated reimbursement rates with network providers? To answer this question, I gathered network reimbursement rates paid by BCBS/MA to its network providers. I find that **those reimbursed amounts were not informed** by and did not reflect the knowledge of ASPs acquired by the HMO side of the business. Instead, BCBS/MA **network reimbursement amounts were related to AWP in the same way as found with claims reimbursed by TPPs without staff model HMOs** and therefore without ASP information provided by staff model HMOs. The only valid conclusion that can drawn from this data analysis is that BCBS/MA's staff-HMO information was simply not shared with and not acted upon in any meaningful way by the claims administration group (the "provider reimbursement group").

6. The data analysis proceeded as follows:

- a) I had my staff gather and analyze the data summarizing claims administered outside of the staff-model HMO setting for BCBS/MA.<sup>1</sup> My analysis of the BCBS/MA claims data focuses upon the period 1994-2003 and summarizes the average reimbursement amounts paid to network providers for a subset of the drugs and J-Codes.<sup>2</sup>
- b) If institutions with staff model providers and network providers could learn share ASP information at the institutional level, I should find the following:
  - For those drugs which it purchased directly, BCBS/MA should have been well-informed concerning acquisition costs and should have been able to make use of that information to negotiate reimbursement rates with network providers that approximated BCBS/MA's EACs (or ASPs). They do not.
  - Even if BCBS/MA staff HMO did not purchase certain physician-administered drugs directly, the pricing and market information that it obtained from its purchase of other physician-administered drugs should have enabled BCBS/MA to aggressively negotiate reimbursement rates with network providers closer to

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<sup>1</sup> BCBS-MA was the only Massachusetts TPP for which data were available.

<sup>2</sup> The drugs that I analyze that were purchased by BCBS/MA include Vepesid, Zofran, Procrit, Blenoxane and Kytril. The drugs that I analyze that BCBS/MA seems not to have purchased directly are Zoladex, Taxol and Remicade. If TPPs can learn and share ASP information, then the reimbursement amounts paid by BCBS/MA for the first set of drugs certainly should track the ASPs rather than AWPs. Likewise, given an expansive belief in the power of available information to enable TPPs to negotiate better reimbursement amounts, I should find that BCBS/MA was able to negotiate reimbursement rates that approximate the ASPs rather than the AWPs of those physician-administered drugs that it did not purchase directly.

The analysis of claims data rejects the hypothesized power of the knowledge of ASP information to negotiate better network reimbursement rates. For the drugs Vepesid, Zofran, Procrit, Kytril, Taxol and Remicade, average reimbursement rates are uniformly very close to or greater than AWP or 95% of AWP. For the drugs Blenoxane and Zoladex, average reimbursement rates are within approximately 15% of AWP, the range found by the *MedPAC Report to the Congress*, June 2003, chapter 9.

drug acquisition costs than to traditional reimbursements formulae based off AWP. They do not do this either.

7. Based upon an analysis of claims data, any hypothesized information advantage to enable BCBS/MA to negotiate better reimbursement rates with network providers **does not exist**. Average reimbursement rates to network providers are either very close to or greater than AWP or they are within approximately 15% of AWP, the range found by the *MedPAC Report*. I conclude the following:

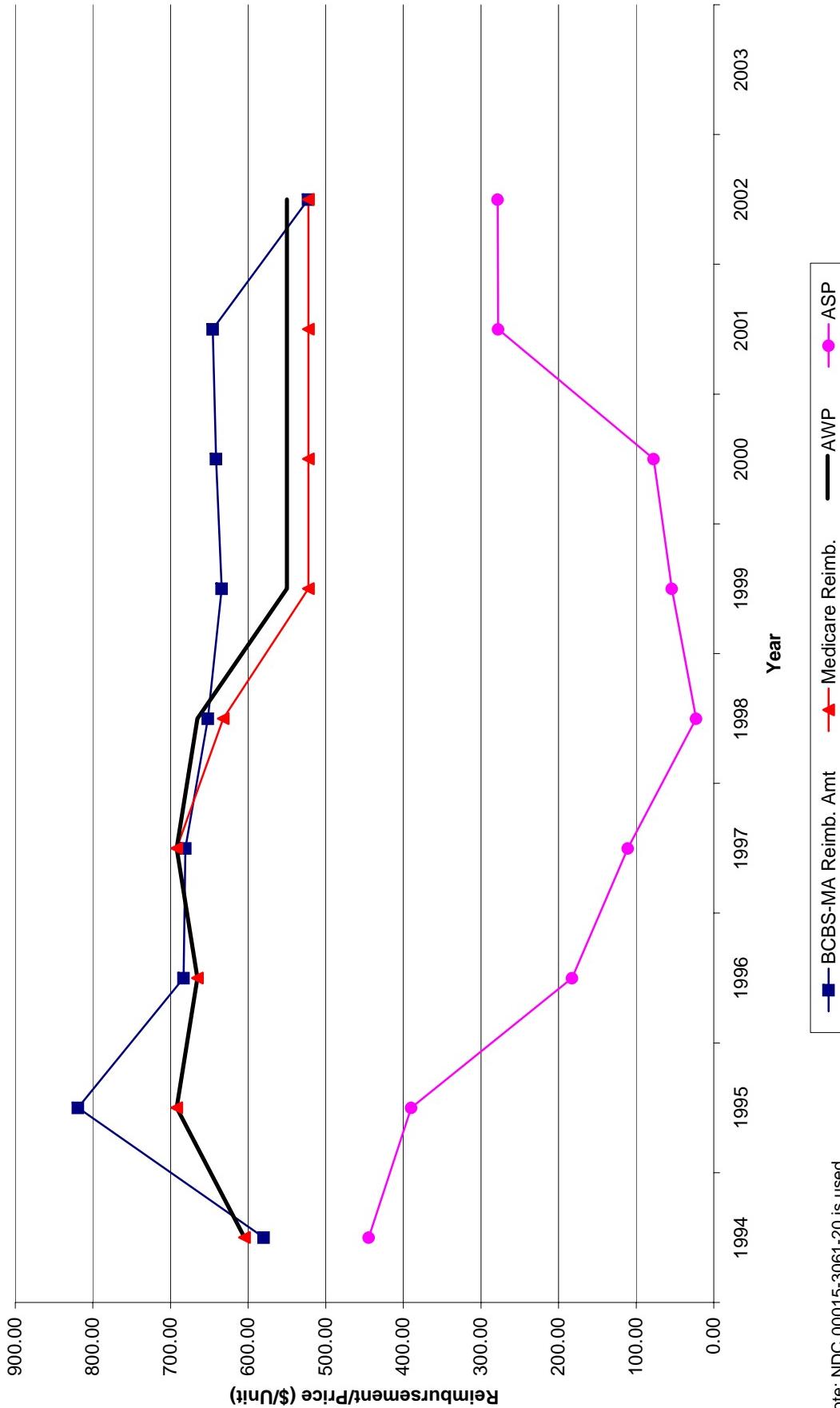
- a) TPPs with subsidiaries or divisions that purchase physician-administered drugs do not make use of that information to better negotiate reimbursement rates for those insured lives that are served by the TPPs network providers.
- b) TPPs with direct purchasing of physician-administered drugs are not better able, or at all able, to avoid the economic impact and injury of the AWP Inflation Scheme.
- c) There is no evidence of **direct learning** by BCBS/MA. Direct learning would occur if a drug purchased by a staff-model HMO informed reimbursement by BCBS/MA to network providers. For those drugs purchased by the BCBS/MA staff-model HMO, the average reimbursement allowed to network providers was based on AWP not ASP. While each drug exhibits some idiosyncratic behavior, the evidence provides a powerful demonstration that the market for pharmaceuticals is characterized by non-transparency **within** private sector health care entities, such as BCBS/MA.
- d) Likewise, and not surprisingly, there is no evidence of **indirect learning** by BCBS/MA. Indirect learning would occur if a staff-model HMO learned of the AWP-ASP spread for a given set of drugs, conveyed that information within the TPP generally, and the TPP's provider reimbursement group extrapolated that knowledge

to gain some inferences about the ASPs related to claims for reimbursement for other drugs. I find that the reimbursement rates for other drugs reimbursed by BCBS/MA track AWP rather than ASP.

To summarize, because some group within an institution has obtained pricing information that could benefit that institution generally, this does not automatically insure that such information will be transmitted to or shared with the division or group (in this case, the provider reimbursement group) that would make use of and benefit from that information. The fact is the healthcare-services group of BCBS/MA obtained information concerning the ASPs of specific physician-administered drugs and did not insure that such information was transmitted to or shared with its provider reimbursement group in a way that BCBS/MA minimized network claim reimbursements, thereby defeating the AWP Inflation Scheme. The analytic results certainly support the theories of institutional economics and the inertia displayed by them.

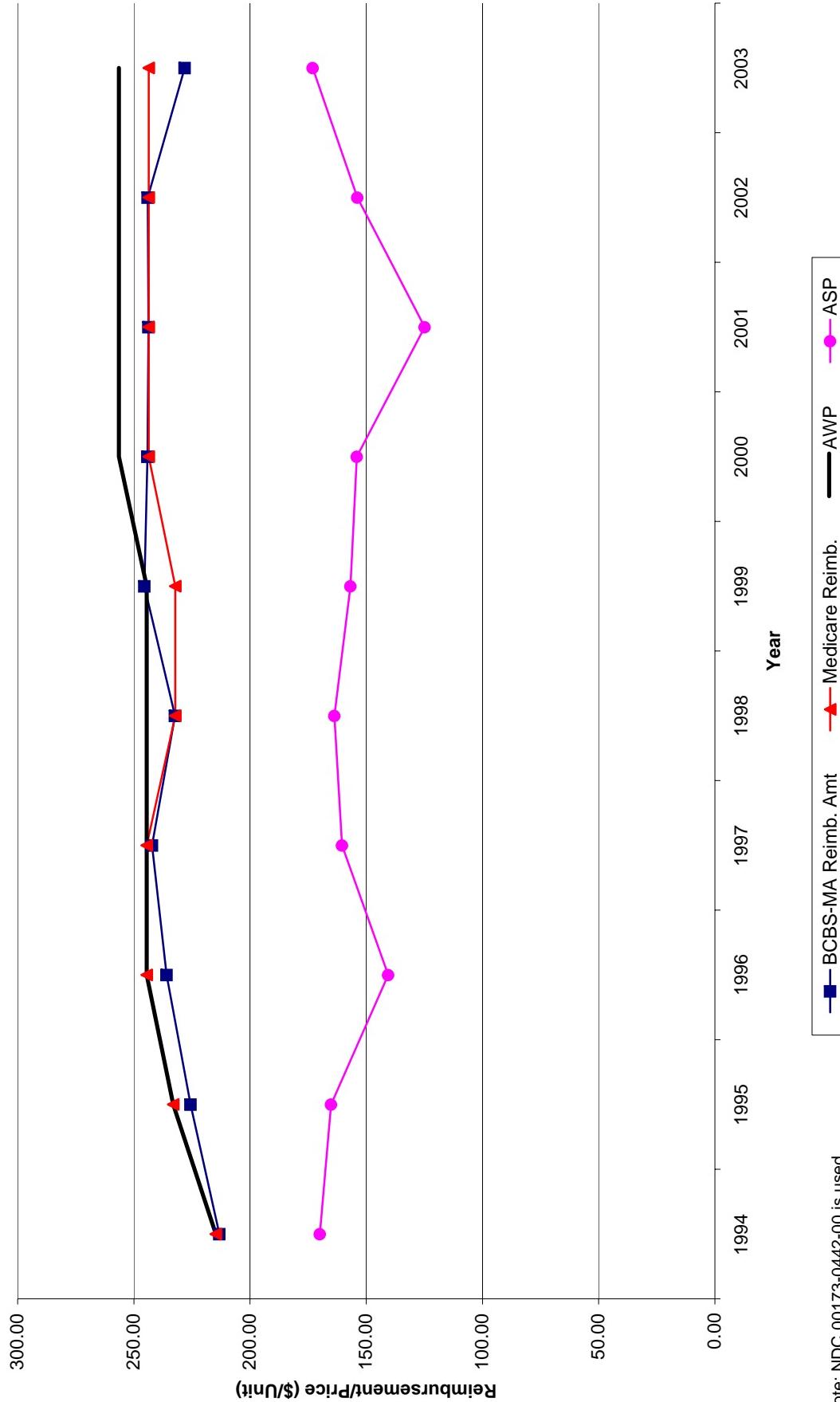
**Attachment F: Claims Analysis Graphs for BCBS-MA**

**Attachment F.1**  
**Comparison of BCBS-MA Reimbursement Amounts for Vepesid (J9181) with AWP and ASP**



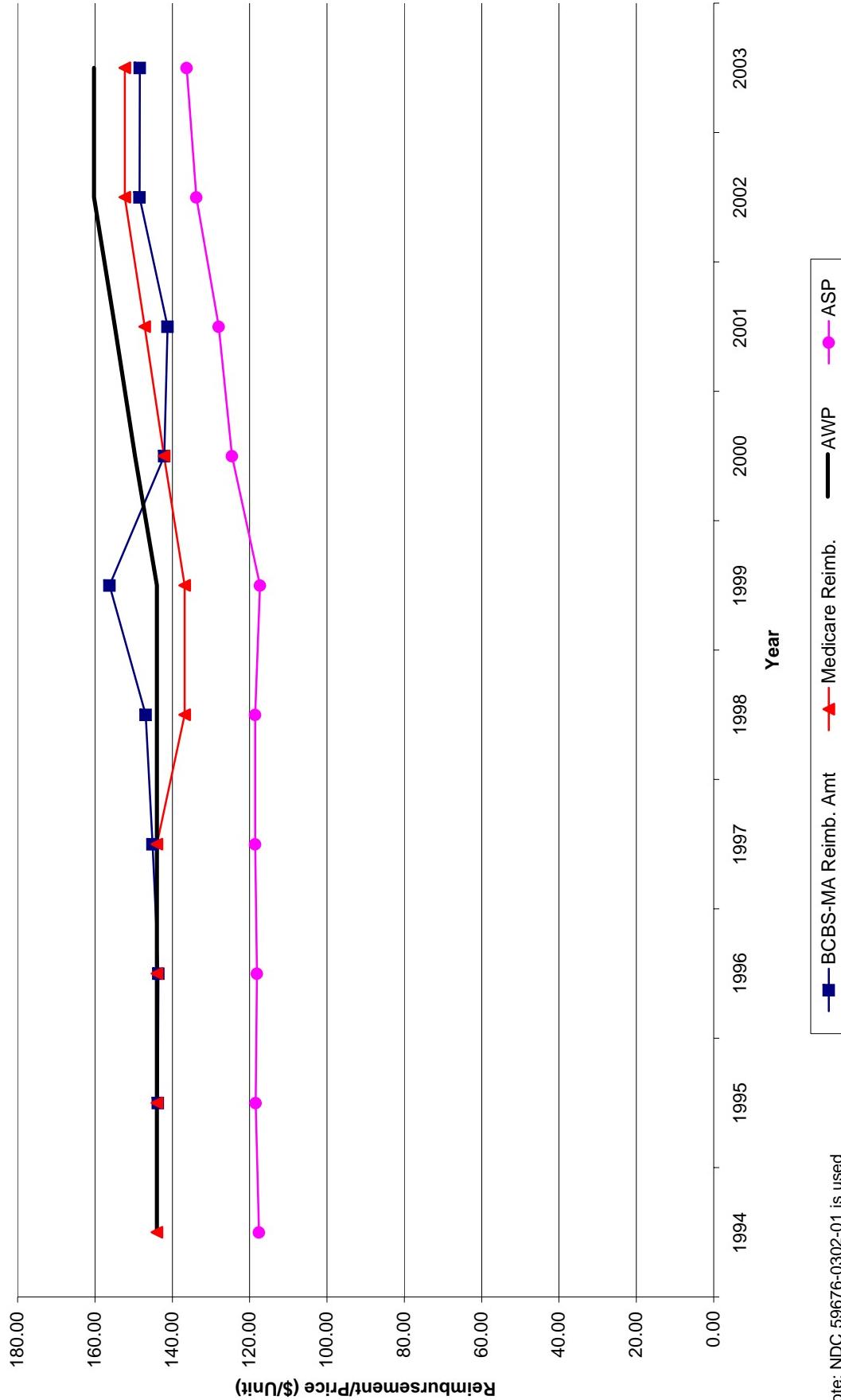
Direct Testimony of Raymond S. Hartman

**Attachment F.2**  
**Comparison of BCBS-MA Reimbursement Amounts for Zofran (J2405) with AWP and ASP**



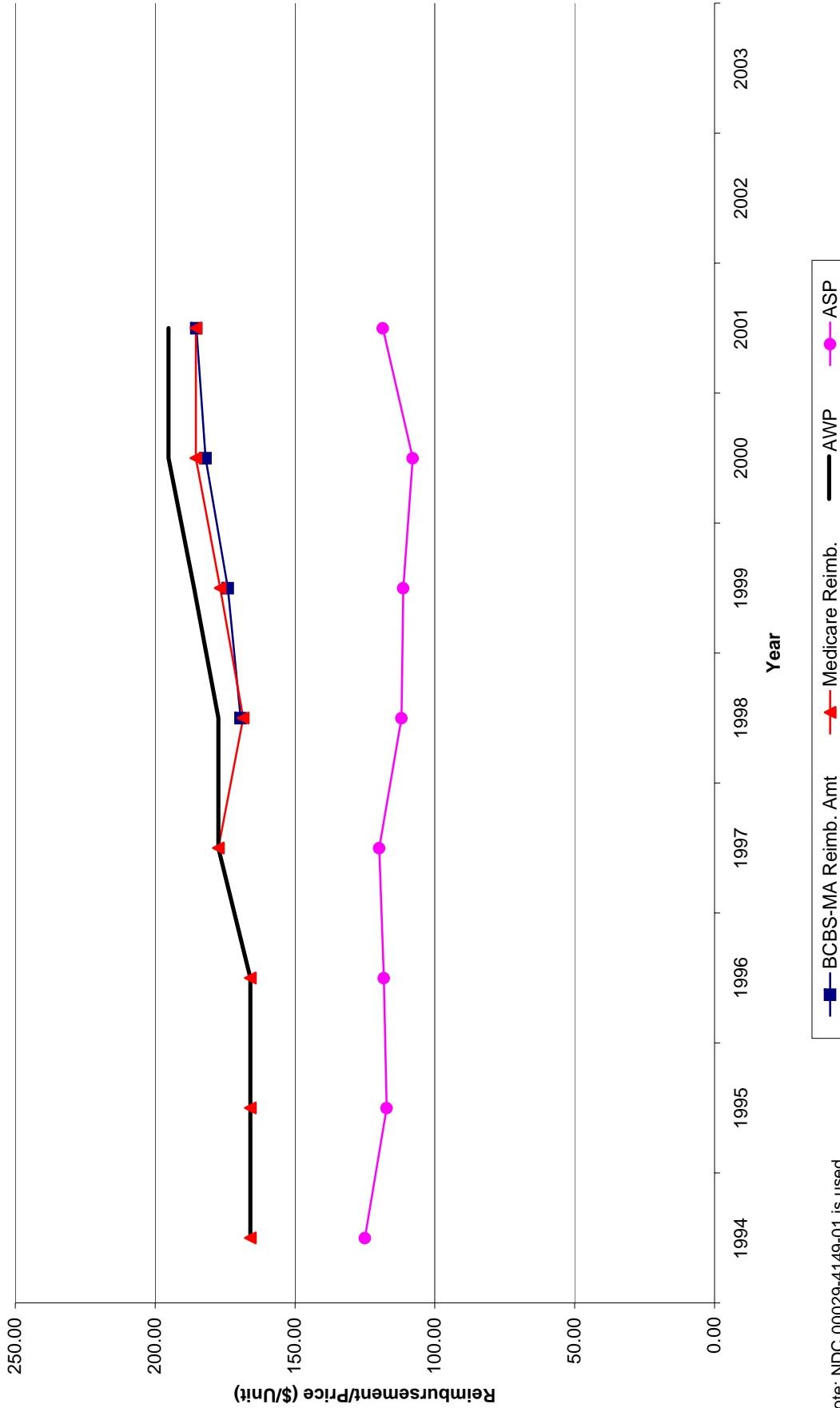
Direct Testimony of Raymond S. Hartman

**Attachment F.3**  
**Comparison of BCBS-MA Reimbursement Amounts for Procrit (Q0136) with AWP and ASP**



Note: NDC 59676-0302-01 is used  
for the AWP and ASP.

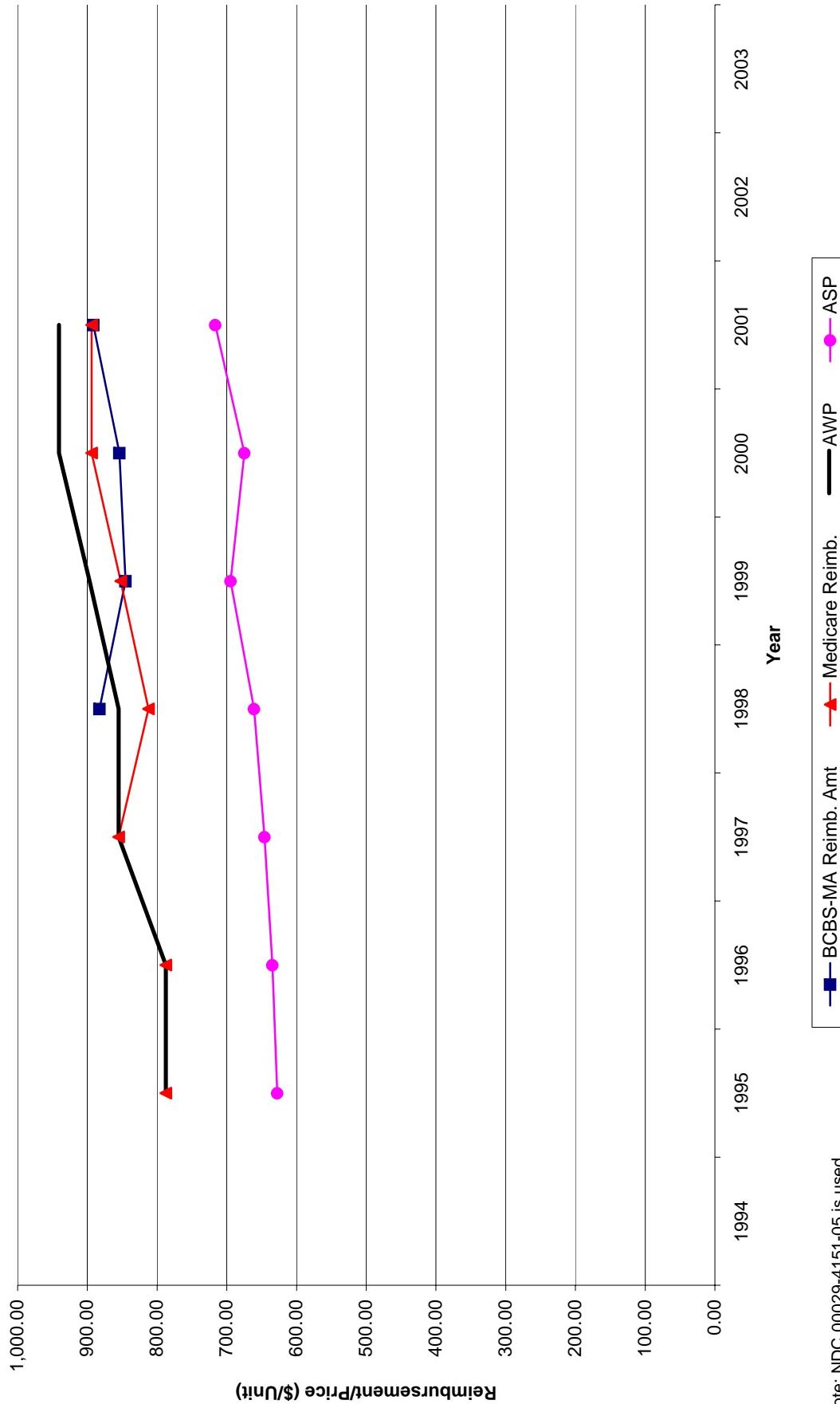
**Attachment F.4**  
**Comparison of BCBS-MA Reimbursement Amounts for Kytril (J1626) with AWP and ASP**



Note: NDC 00029-4149-01 is used  
for the AWP and ASP.

Direct Testimony of Raymond S. Hartman

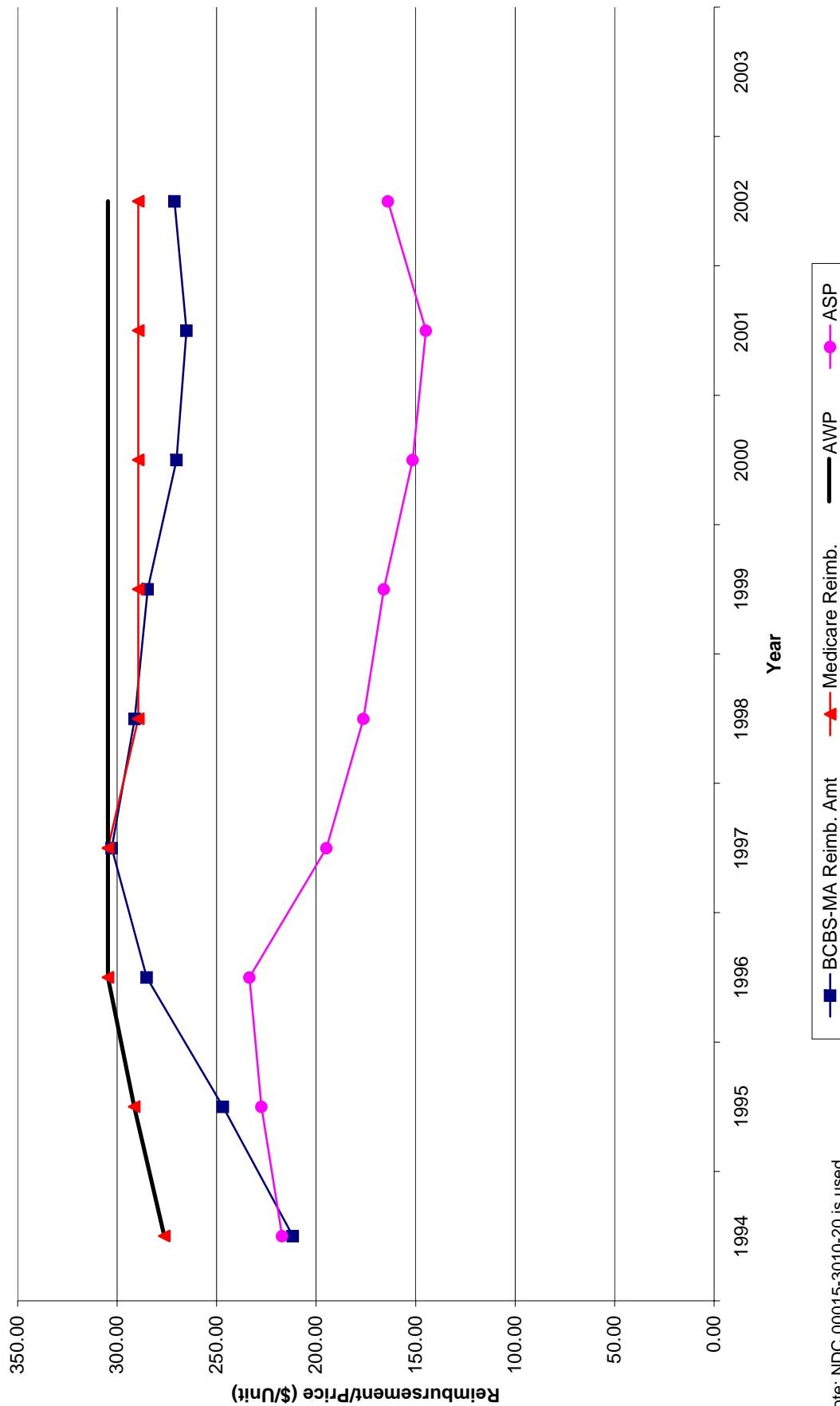
**Attachment F.5**  
**Comparison of BCBS-MA Reimbursement Amounts for Kytril (Q0166) with AWP and ASP**



Note: NDC 00029-4151-05 is used  
for the AWP and ASP.

Direct Testimony of Raymond S. Hartman

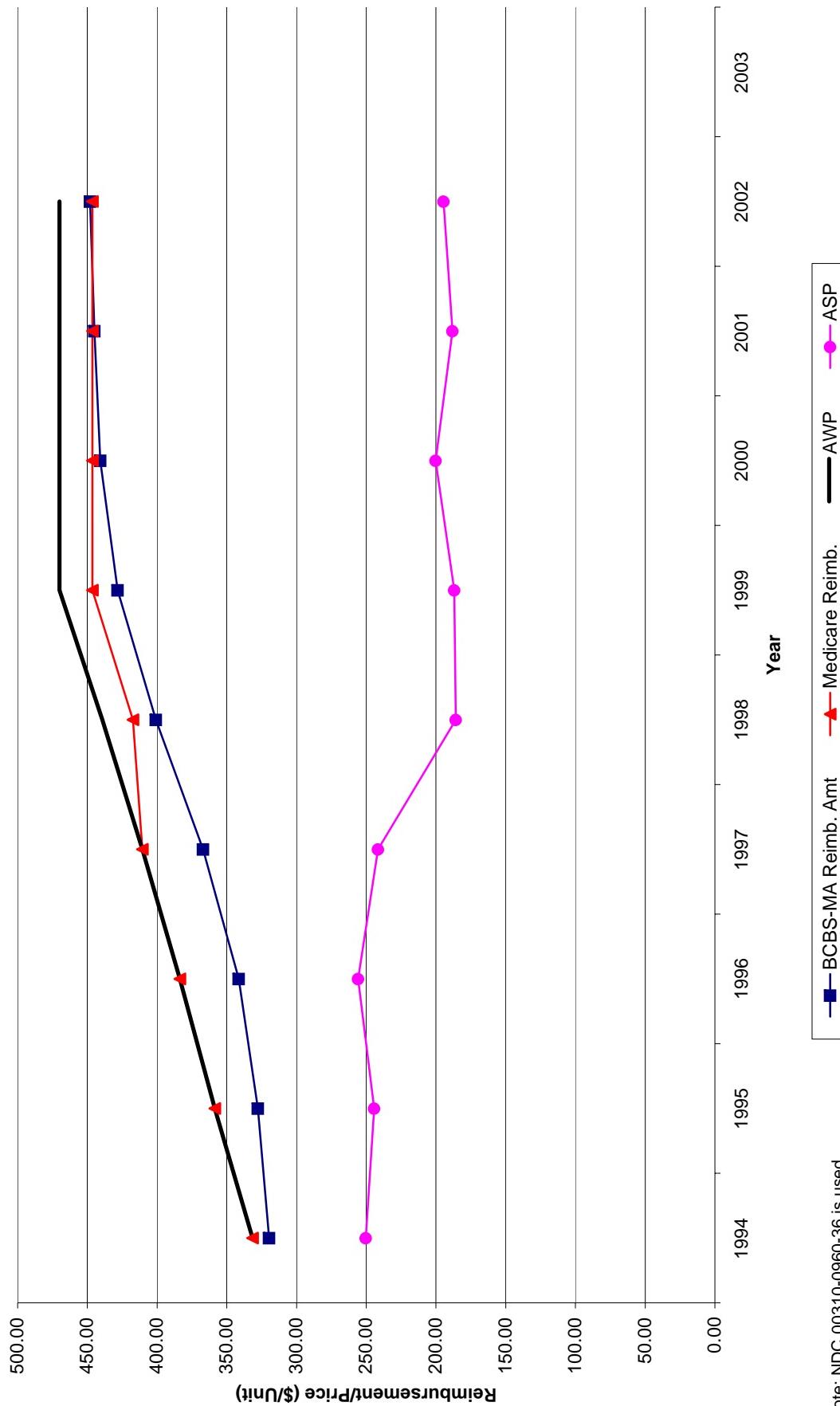
**Attachment F.6**  
**Comparison of BCBS-MA Reimbursement Amounts for Blenoxane (J9040) with AWP and ASP**



Note: NDC 00015-3010-20 is used  
for the AWP and ASP.

Direct Testimony of Raymond S. Hartman

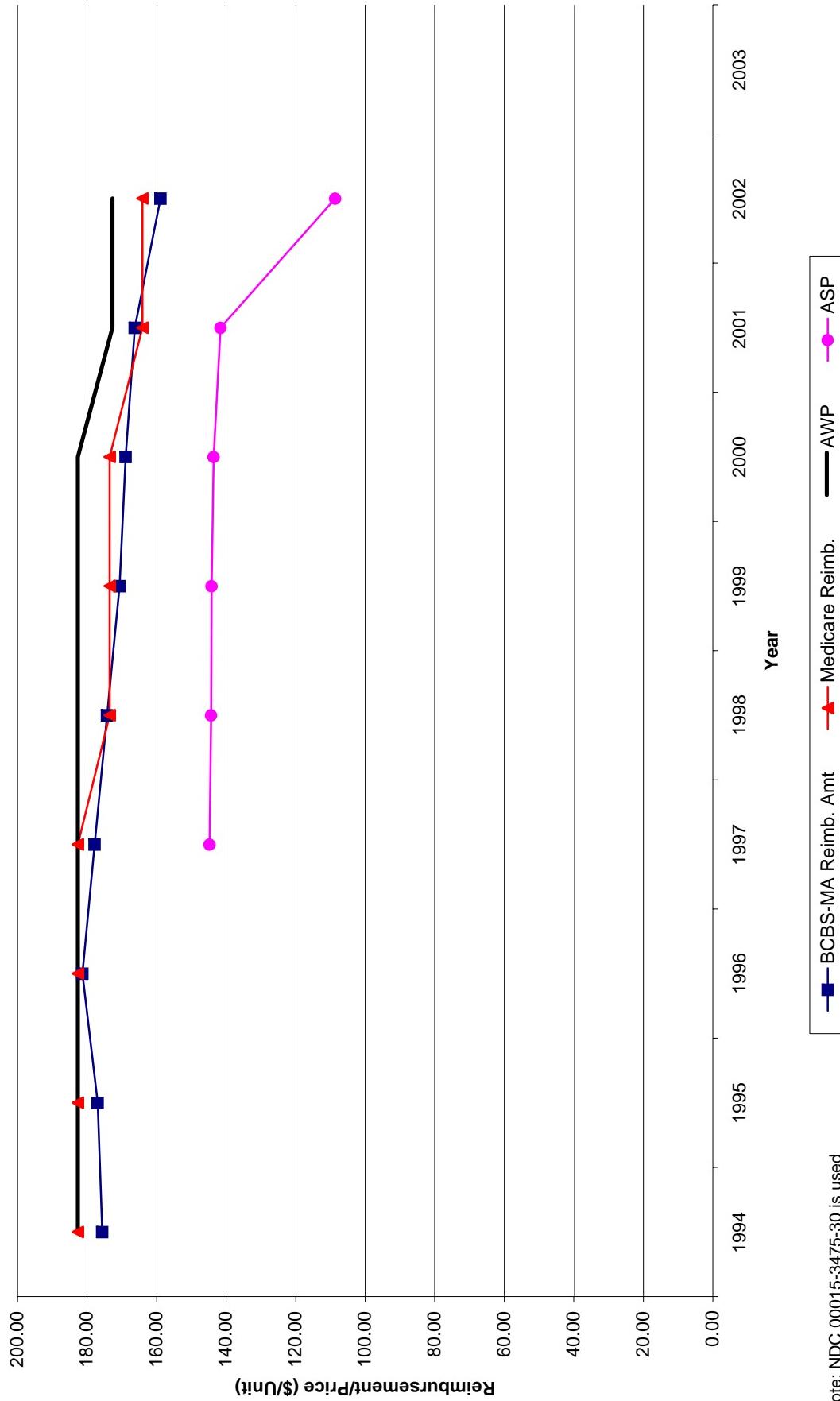
**Attachment F.7**  
**Comparison of BCBS-MA Reimbursement Amounts for Zoladex (J9202) with AWP and ASP**



Note: NDC 00310-0960-36 is used  
for the AWP and ASP.

Direct Testimony of Raymond S. Hartman

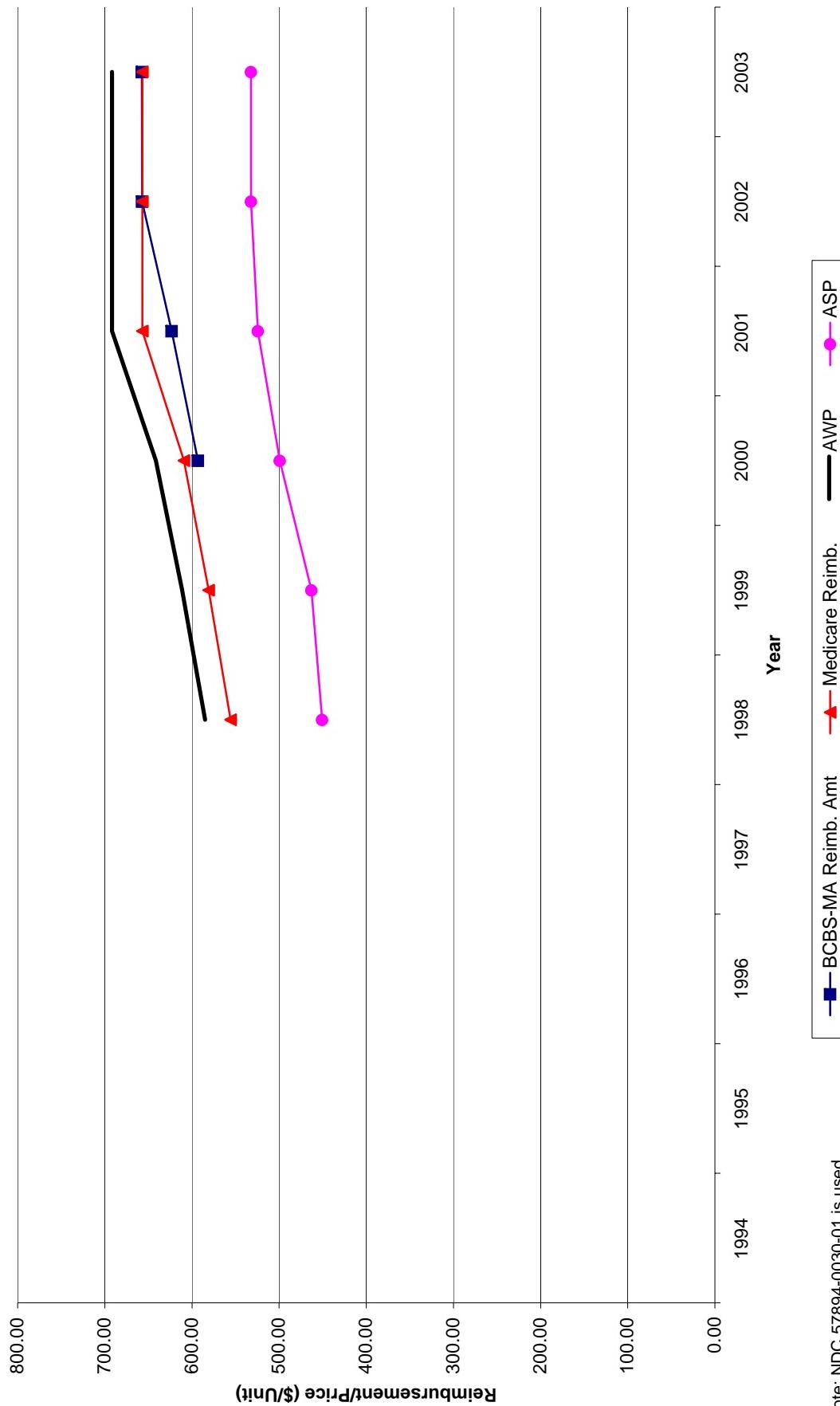
**Attachment F.8**  
**Comparison of BCBS-MA Reimbursement Amounts for Taxol (J9265) with AWP and ASP**



Note: NDC 00015-3475-30 is used  
for the AWP and ASP.

Direct Testimony of Raymond S. Hartman

**Attachment F.9**  
**Comparison of BCBS-MA Reimbursement Amounts for Remicade (J1745) with AWP and ASP**



Direct Testimony of Raymond S. Hartman

**Attachment G: Spreads, ASPs and AWPs by Defendant**

**Attachment G.1.a: AstraZeneca Annual Average Sales Price**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
			1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	255.00	254.95	263.67	250.37	244.38	255.90	241.63	185.87	186.83	200.34	188.21	194.62		
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot						796.01	684.46	517.59	523.55	537.78	538.75	537.90		

**Attachment G.1.b: AstraZeneca Annual AWPs**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	318.75	318.75	318.75	331.50	358.55	383.65	410.51	439.24	469.99	469.99	469.99	469.99	469.99	469.99
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot				1,208.49	1,231.53	1,317.74	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98

**Attachment G.1.c: AstraZeneca Annual Spreads**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	25.00%	25.03%	20.89%	32.40%	46.72%	49.92%	69.89%	136.31%	151.56%	134.60%	149.71%	141.49%		
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot					51.82%	79.93%	154.59%	169.31%	162.18%	161.72%	162.13%			

## **Attachment G 2.a: Bristol-Myers Squibb Annual Average Sales Price**

**Attachment G.2.a: Bristol-Myers Squibb Annual Average Sales Price**

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347911	Taxol	TAXOL 300MG/50ML VIAL	496.75	444.63	389.79	182.70	110.84	1,427.42	1,431.68	1,428.46	1,370.01	832.23
00015306120	Vepesid	VEPESID 500MG						22.85	54.02	77.46	277.96	278.63
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA	915.33	879.80	728.28	366.66	173.02	19.29	532.30	529.60	433.31	
00015306220	Vepesid	VEPESID 1GM/50ML							99.65	164.75	244.56	253.11
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+	160.24	146.80	122.88	59.65	37.33	867.64	839.73	841.39		
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML	532.99	538.71	550.65	571.13	604.56	644.98	707.97	798.99	862.77	942.42
00015309145	Vepesid	VEPESID 50MG CAPSULES										
00015309510	Vepesid	VEPESID 100MG VIAL W/CYTO	107.35	108.22								
00015309520	Vepesid	VEPESID INJ 100MG/5ML	105.70	96.94	75.44	27.77						
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO	109.19	109.18	109.15	108.00	102.89	102.11				

**Attachment G.2.b: Bristol-Myers Squibb Annual AWPs**

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015301020	Blenoxane	BLENOXANE INJ 15 UNIT VL	265.66	276.29	291.49	304.60	304.60	304.60	304.60	304.60	304.60	304.60
00015301026	Blenoxane	BLENOXANE INJ 15 UNIT VHA				304.60	304.60	304.60	304.60	304.60	304.60	304.60
00015306301	Blenoxane	BLENOXANE INJ 30 UNIT VL				609.20	609.20	609.20	609.20	609.20	609.20	609.20
00015306326	Blenoxane	BLENOXANE INJ 30 UNIT VHA				609.20	609.20	609.20	609.20	609.20	609.20	609.20
00015050001	Cytoxan	CYTOKAN FOR INJ 100 MG										
00015050041	Cytoxan	CYTOKAN INJ 100MG	4.91	5.11	5.31	5.31						
00015050141	Cytoxan	CYTOKAN INJ 200MG	9.34	9.73	10.11	10.11						
00015050241	Cytoxan	CYTOKAN INJ 1X50MG VIAL	19.61	20.43	15.25	15.25	15.25	15.25	15.25	15.25	15.25	15.25
00015050301	Cytoxan	CYTOKAN TABS 50MG	265.34	275.95	291.13	304.23	317.91	342.18	389.68	431.66	431.66	431.66
00015050302	Cytoxan	CYTOKAN TABLETS 50MG	2,527.10	2,628.19	2,772.74	2,897.51	3,027.90	3,259.08	3,711.44	4,111.35	4,111.35	4,111.35
00015050303	Cytoxan	CYTOKAN TABLETS 50 MG	303.90	315.45								
00015050348	Cytoxan	CYTOKANTABS 50MG										
00015050401	Cytoxan	CYTOKAN TABS 25MG										
00015050541	Cytoxan	CYTOKAN PINJ X1G VIAL	39.22	40.85	42.49	42.49	42.49	42.49	42.49	42.49	42.49	42.49
00015050641	Cytoxan	CYTOKAN INJ 1X2GM VIAL	78.46	81.73	85.00	85.00	85.00	85.00	85.00	85.00	85.00	85.00
00015053910	Cytoxan	CYTOKAN 100MG LYOPH W/CYT										
00015053941	Cytoxan	CYTOKAN LYOPHILIZED 100MG	6.20	6.20	6.45	6.45	6.45	6.45	6.45	6.45	6.45	6.45
00015054610	Cytoxan	CYTOKAN 200MG LYOPH W/CYT	11.78	11.78	12.25	12.25	12.25	12.25	12.25	12.25	12.25	12.25
00015054641	Cytoxan	CYTOKAN LYOPHILIZED 200MG	11.78	11.78	12.25	12.25	12.25	12.25	12.25	12.25	12.25	12.25
00015054710	Cytoxan	CYTOKAN 500MG LYOPH W/CYT	24.73	24.73	25.71	25.71	25.71	25.71	25.71	25.71	25.71	25.71
00015054712	Cytoxan	CYTOKAN 500MG VL VHA										
00015054741	Cytoxan	CYTOKAN LYOPH 500MG	24.73	24.73	25.71	25.71	25.71	25.71	25.71	25.71	25.71	25.71
00015054810	Cytoxan	CYTOKAN 1GMLYOPH W/CYT	49.45	44.95								
00015054812	Cytoxan	CYTOKAN 1G 6X50ML VHA+										
00015054841	Cytoxan	CYTOKAN LYOPHILIZED 1GM	49.45	44.95	51.43	51.43	51.43	51.43	51.43	51.43	51.43	51.43
00015054910	Cytoxan	CYTOKAN 2GM LYOPH W/CYT	98.93	98.93								
00015054912	Cytoxan	CYTOKAN LYOPH 500MG VL										
00015054941	Cytoxan	CYTOKAN LYOPHILIZED 2GM										
00015340420	Etopophos	ETOPOPHOS 100MG VIAL										
00015321310	Paraplatin	PARAPLATIN 50MG W/CYT	75.00	78.00								
00015321329	Paraplatin	PARAPLATIN 10X5ML VHA+	75.00	78.00	81.13	84.78	88.59	100.11	100.11	100.31	100.31	100.31
00015321330	Paraplatin	PARAPLATIN 50MG LYOPHILIZ	224.96	233.96	243.33	254.28	265.71	288.74	300.29	300.29	327.91	327.91
00015321410	Paraplatin	PARAPLATIN 1X45ML LYOPH CY										
00015321429	Paraplatin	PARAPLATIN 10X15ML VHA+	224.96	233.96	243.33	254.28	265.71	288.74	312.30	312.30	327.91	327.91
00015321430	Paraplatin	PARAPLATIN 1X150MG LYO VL	674.90	701.90								
00015321510	Paraplatin	PARAPLATIN 450MG VL W/CYT										
00015321529	Paraplatin	PARAPLATIN 10X45ML VHA+										
00015321530	Paraplatin	PARAPLATIN 1X450MG LYO VL	674.90	701.90	729.98	762.83	797.15	800.86	900.86	983.75	983.75	1,084.19
00015335122	Rubex	RUBEX 100MG IMMUNEX LABEL			43.81	43.81						
00015335124	Rubex	RUBEX 10MG IMMUNEX LABEL			43.81	43.81						
00015335222	Rubex	RUBEX 50MG LYOPHILIZED	189.26	189.26	197.15	197.15	197.15	197.15	197.15	197.15	197.15	197.15
00015335224	Rubex	RUBEX 100 MG LYOPHILIZED	378.52	378.52	394.29	394.29	394.29	394.29	394.29	394.29	394.29	394.29
00015335227	Rubex	RUBEX 100MG IMMUNEX LABEL										
00015347520	Taxol	TAXOL 30MG CONC FOR INJ	182.63	182.63								
00015347527	Taxol	TAXOL 30MG V5ML VHA+ LABEL										
00015347530	Taxol	TAXOL 30MG SEM-SYN VIAL	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63
00015347620	Taxol	TAXOL 100MG 16.7ML VHA+ L										
00015347627	Taxol	TAXOL 100MG SEM-SYN VIAL										

**Attachment G.2.b: Bristol-Myers Squibb Annual AWPs**

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347630	Taxol	TAXOL 100MG INJ MULTIDOSE				608.76	608.76	608.76	608.76	608.76	608.76	608.76
00015347911	Taxol	TAXOL 300MG/50ML VIAL	665.38	665.38	665.38	665.38	665.38	1,826.25	1,826.25	1,826.25	1,826.25	1,826.25
00015306120	Vepesid	VEPESID 500MG						665.38	665.38	665.38	665.38	665.38
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64
00015306220	Vepesid	VEPESID 1GM/50ML										
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+	204.74	204.74	204.74	204.74	204.74	204.74	204.74	204.74	204.74	204.74
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML	674.68	674.68	694.91	719.24	751.60	808.99	921.28	1,020.54	1,103.71	1,192.01
00015309145	Vepesid	VEPESID 50MG CAPSULES	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49
00015309510	Vepesid	VEPESID 100MG VIAL W/CYTO										
00015309520	Vepesid	VEPESID INJ 100MG/5ML	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49

**Attachment G.2.c: Bristol-Myers Squibb Annual Spreads**

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015301020	Blenoxane	BLENOXANE INJ 15 UNIT VL	27.1%	27.2%	28.1%	30.4%	56.4%	72.8%	83.6%	101.1%	110.3%	85.9%
00015301026	Blenoxane	BLENOXANE INJ 15 UNIT VHA				25.0%	27.3%	31.7%	26.5%	30.1%	30.1%	25.0%
00015306301	Blenoxane	BLENOXANE INJ 30 UNIT VL				28.8%	77.6%	71.1%	76.4%	153.1%	172.0%	199.0%
00015306326	Blenoxane	BLENOXANE INJ 30 UNIT VHA				25.0%	25.0%	33.7%	43.8%	44.4%	33.3%	25.0%
00015050001	Cytoxan	CYTOKAN FOR INJ 100 MG	27.5%	28.1%	30.0%	27.4%						
00015050041	Cytoxan	CYTOKAN INJ 100MG	32.4%	31.6%	32.7%	50.9%						
00015050141	Cytoxan	CYTOKAN INJ 1X500MG VIAL	29.5%	33.6%	1.8%							
00015050241	Cytoxan	CYTOKAN TABS 50MG	26.2%	26.5%	26.9%							
00015050301	Cytoxan	CYTOKAN TABLETS 50MG	26.4%	26.3%	27.6%							
00015050302	Cytoxan	CYTOKAN TABLETS 50 MG	21.4%	23.6%								
00015050303	Cytoxan	CYTOKAN TABS 50 MG										
00015050348	Cytoxan	CYTOKAN TABS 25MG	26.2%	26.7%	26.9%	25.7%	24.4%	25.4%	31.0%	27.4%	25.7%	38.6%
00015050401	Cytoxan	CYTOKAN PINJ 1X1G VIAL	53.4%	48.2%	170.9%	69.7.5%						
00015050541	Cytoxan	CYTOKAN INJ 1X2GM VIAL	108.4%	155.1%								
00015050590	Cytoxan	CYTOKAN 100MG LYOPH W/CYT	32.6%	33.5%	61.8%	72.0%	97.8%	145.4%	121.5%	179.7%	78.3%	77.2%
00015053941	Cytoxan	CYTOKAN 200MG LYOPH W/CYT	35.9%	31.3%	52.3%	64.9%	69.9%	164.0%	208.4%	285.3%	192.5%	100.2%
00015054610	Cytoxan	CYTOKAN LYOPHILIZED 200MG										80.1%
00015054641	Cytoxan	CYTOKAN LYOPH W/CYT	33.3%	27.5%								
00015054710	Cytoxan	CYTOKAN 500MG LYOPH W/CYT										
00015054712	Cytoxan	CYTOKAN LYOPH 500MG VL VHA	50.7%	69.0%	99.4%	188.3%	209.7%	296.8%	30.0%	398.8%	119.2%	64.5%
00015054741	Cytoxan	CYTOKAN LYOPH 500MG VL	37.2%	19.9%								
00015054810	Cytoxan	CYTOKAN 1G 6X50ML VHA+										
00015054812	Cytoxan	CYTOKAN LYOPHILIZED 1GM										
00015054841	Cytoxan	CYTOKAN 2GM LYOPH W/CYT	38.9%	34.7%	69.7%	83.9%	157.7%	257.7%	325.3%	676.8%	248.4%	132.1%
00015054910	Cytoxan	CYTOKAN LYOPH 500ML VHA+										
00015054912	Cytoxan	CYTOKAN 2G 6X100ML VHA+										
00015054941	Cytoxan	CYTOKAN LYOPHILIZED 2GM										
00015340420	Etopophos	ETOPOPHOS 100MG VIAL	27.8%	29.3%		35.8%	27.0%	372.2%	559.2%	465.3%	519.3%	171.2%
00015321310	Paraplatin	PARAPLATIN 50MG W/CYT O										25.1%
00015321329	Paraplatin	PARAPLATIN 10X5ML VHA+										
00015321330	Paraplatin	PARAPLATIN 10X5ML LYOPHILIZ	28.4%	27.3%	28.6%	28.1%	45.8%	27.5%	35.2%	67.5%	27.2%	21.4%
00015321410	Paraplatin	PARAPLATIN 150MG LYOPH CY	27.6%	29.9%								
00015321429	Paraplatin	PARAPLATIN 10X15ML VHA+										
00015321430	Paraplatin	PARAPLATIN 1X150MG LYO VL	28.4%	27.3%	28.3%	28.0%	24.9%	27.8%	35.3%	24.9%	26.2%	39.5%
00015321510	Paraplatin	PARAPLATIN 450MG VL W/CYT	27.5%	30.0%								
00015321529	Paraplatin	PARAPLATIN 10X45ML VHA+										
00015321530	Paraplatin	PARAPLATIN 1X450MG LYO VL	28.8%	27.0%	28.1%	27.9%	24.9%	33.6%	30.2%	27.8%	65.4%	38.0%
00015335122	Rubex	RUBEX 10MG IMMUNEX LABEL		193.9%	205.5%							
00015335124	Rubex	RUBEX 10MG LYOPHILIZED	25.0%									
00015335222	Rubex	RUBEX 50MG IMMUNEX LABEL										
00015335224	Rubex	RUBEX 50MG LYOPHILIZED	27.0%									
0001533522	Rubex	RUBEX 100 MG LYOPHILIZED	343.8%	210.4%	278.8%	395.9%	223.2%	171.7%			37.0%	26.6%
0001533524	Rubex	RUBEX 100MG IMMUNEX LABEL	58.7%	26.1%	26.6%							
00015345620	Taxol	TAXOL 30MG CONC FOR INJ	25.5%									
00015347520	Taxol	TAXOL 30MG/5ML VHA+ LABEL										
00015347527	Taxol	TAXOL 30MG SEM-SYN VIAL										
00015347530	Taxol	TAXOL 30MG INJ MULTIDOSE										
00015347620	Taxol	TAXOL 100MG/16.7ML VHA+ L										
00015347627	Taxol	TAXOL 100MG SEM-SYN VIAL										

**Attachment G.2.c: Bristol-Myers Squibb Annual Spreads**

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347630	Taxol	TAXOL 100MG INJ MULTIDOSE					27.0%	27.1%	27.0%	27.4%	29.1%	128.7%
000153067911	Taxol	TAXOL 300MG/50ML VIAL	33.9%	49.6%	70.7%	264.2%	500.3%	2812.4%	1131.7%	27.6%	27.8%	33.3%
00015306120	Vepesid	VEPESID 500MG										119.4%
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA										139.4%
00015306220	Vepesid	VEPESID 1GM/50ML	41.7%	47.4%	78.0%	253.6%	649.4%	6621.9%	1201.2%	25.0%	25.6%	53.6%
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+										430.2%
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML	27.8%	39.5%	66.6%	243.2%	448.5%	24.3%	49.4%	54.4%	54.1%	114.6%
00015309145	Vepesid	VEPESID 50MG CAPSULES	26.6%	25.2%	26.2%	25.9%	24.3%	25.4%	30.1%	296.2%	187.9%	26.5%
00015309510	Vepesid	VEPESID 100MG VIAL W/CYTO	27.1%	26.1%						27.7%	27.7%	27.9%
00015309520	Vepesid	VEPESID INJ 100MG/5ML	29.1%	40.8%	80.9%	391.5%				225.8%	121.3%	
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO	25.0%	25.0%	25.0%	26.4%	32.7%	33.7%		36.9%	39.8%	

Attachment G.3.a: Johnson & Johnson Annual Average Sales Price

**Attachment G.3.b: Johnson & Johnson Annual AWP's**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG	288.00	288.00	288.00										
00062740103	Procrit	PROCRIT 1000U/ML AMG	684.00	684.00	684.00										
00062740201	Procrit	PROCRIT 2000U/ML AMG	144.00	144.00	144.00										
00062740501	Procrit	PROCRIT 3000U/ML AMG	216.00	216.00	216.00										
59676030201	Procrit	PROCRIT 2000 U/ML 6'S	144.00	144.00	144.00										
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTO	600.00	600.00	600.00										
59676030301	Procrit	PROCRIT 3000 U/ML 6'S	216.00	216.00	216.00										
59676030302	Procrit	PROCRIT 3000 U/ML 25'S	900.00	900.00	900.00										
59676030401	Procrit	PROCRIT 4000 U/ML 6'S	288.00	288.00	288.00										
59676030402	Procrit	PROCRIT 4000 U/ML 25'S	1,200.00	1,200.00	1,200.00										
59676031001	Procrit	PROCRIT 10000 U/ML 6'S	684.00	684.00	684.00										
59676031002	Procrit	PROCRIT 10000 U/ML 25'S	2,850.00	2,850.00	2,850.00										
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS	1,368.00	1,368.00	1,368.00										
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML													
59676034001	Procrit	PROCRIT 40000 U/ML 4'S													
57894003001	Remicade	C168J REMICADE 1PCK US PD													

**Attachment G.3.c: Johnson & Johnson Annual Spreads**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	
00062740003	Procrit	PROCRIT 4000U/ML AMG	22.6%	23.7%	21.8%											
00062740103	Procrit	PROCRIT 1000U/ML AMG	22.8%	23.0%	22.8%											
00062740201	Procrit	PROCRIT 2000U/ML AMG	24.4%	24.8%	22.3%											
00062740501	Procrit	PROCRIT 3000U/ML AMG	21.0%	25.2%	21.4%											
59676030201	Procrit	PROCRIT 200 U/ML , INSTITUTO				20.5%	21.4%	21.6%	21.5%	21.4%	22.8%	20.1%	21.0%	19.8%	17.6%	
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTO					20.5%	22.0%	25.2%	24.7%	22.7%	19.0%	24.1%	27.6%	21.8%	
59676030301	Procrit	PROCRIT 3000 U/ML 6'S					21.5%	22.7%	22.1%	21.7%	21.5%	22.5%	20.9%	21.4%	20.5%	
59676030302	Procrit	PROCRIT 3000 U/ML 25'S						22.5%	23.4%	24.4%	23.6%	22.1%	19.3%	22.9%	24.6%	
59676030401	Procrit	PROCRIT 4000 U/ML 6'S						22.7%	21.6%	21.7%	21.2%	21.0%	22.2%	20.9%	20.8%	
59676030402	Procrit	PROCRIT 4000 U/ML 25'S							23.4%	24.2%	25.3%	23.0%	22.6%	19.4%	22.9%	19.1%
59676031001	Procrit	PROCRIT 10000 U/ML 6'S							22.8%	22.5%	22.1%	21.5%	23.2%	21.5%	21.1%	21.1%
59676031002	Procrit	PROCRIT 10000 U/ML 25'S								21.8%	22.4%	22.0%	21.4%	22.0%	20.7%	20.7%
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS									22.3%	25.6%	25.5%	25.4%	23.5%	24.4%
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML										24.9%	25.0%	24.8%	23.7%	24.3%
59676034001	Procrit	PROCRIT 40000 U/ML 4'S											25.6%	25.2%	26.3%	26.0%
57894003001	Remicade	C168J REMICADE 1PCK US PD											24.4%	24.7%	26.0%	26.0%
													29.8%	28.5%	31.9%	29.9%
															30.0%	

**Attachment G.4.a: Schering-Plough Annual Average Sales Price**

NDC	Description	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004Q1
59930151504	Albuterol	ALBUTEROL INHALATION SOLUTION	6.03	6.15	6.55	6.05	4.82	4.27	3.77	3.25	2.98	2.88				
59930164702	Albuterol	ALBUTEROL INHALATION SOLUTION	30.00	30.32	27.79	25.87	18.06	16.83	17.17	13.18	11.77	10.67	2.87	2.60	2.40	
59930150006	Albuterol	ALBUTEROL SULFATE INHAL. SOL.	13.67	12.86	10.54	8.72	7.19	6.43	5.94	4.87	4.67	4.03				
59930150008	Albuterol	ALBUTEROL SULFATE INHAL. SOL.										3.79	3.13	2.62		
59930151701	Albuterol	ALBUTEROL SULFATE SOLUTION										11.11	9.16			
59930151702	Albuterol	ALBUTEROL SULFATE SOLUTION	8.85													
599301556020	Albuterol	ALBUTEROL SULFATE SOLUTION														
00085123501	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085124201	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085125401	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085116801	Intron	INTRON A INJ 1.8MIU HSA FREE														
00085113301	Intron	INTRON A INJ 2.5MIU HSA FREE														
00085118401	Intron	INTRON A INJ 3MIU HSA FREE														
00085118402	Intron	INTRON A INJ 3MIU HSA FREE														
00085119101	Intron	INTRON A INJ 5MIU HSA FREE														
00085119102	Intron	INTRON A INJ 5MIU HSA FREE														
00085117901	Intron	INTRON A INJ PAK10MIU HSA FREE														
00085117902	Intron	INTRON A INJ PAK10MIU HSA FREE														
00085057102	Intron	INTRON A INJECTABLE 10MILLIU	63.56	66.67	75.00	79.51	85.10	89.51	97.75	537.58	163.36	170.08	181.33	180.07	202.47	215.11
00085057106	Intron	INTRON A INJECTABLE 10MILLIU	418.32	416.62	451.57	478.75	537.58	562.16	593.58	93.06	92.18	97.34	100.85	106.11	115.27	122.43
0008511001	Intron	INTRON A INJECTABLE 18MILLIU	146.02	152.50	175.76	197.63	212.05	212.42	217.56	231.80	231.80	256.81	257.07	270.45		
00085028902	Intron	INTRON A INJECTABLE 25MILLIU	20.60	22.19	23.69	24.82	25.78	26.91	28.05	28.42	29.02					
00085064703	Intron	INTRON A INJECTABLE 3MILLIU	20.94	22.12	23.30	24.50	25.79	26.83	27.44							
00085064704	Intron	INTRON A INJECTABLE 3MILLIU	119.09	118.87	131.16	140.02	148.03	160.54	166.53	172.08	173.84	183.95	146.23			
00085064705	Intron	INTRON A INJECTABLE 5MILLIU	33.90	36.91	39.24	41.35	42.85	44.71	46.76	47.08	49.92	50.89	54.36	55.40		
00085012002	Intron	INTRON A INJECTABLE 5MILLIU	29.88	32.91	36.84	39.11	42.28	43.67								
00085012003	Intron	INTRON A INJECTABLE 5MILLIU	477.49	509.90	534.88	563.63	564.86									
00085012004	Intron	INTRON A INJECTABLE 5MILLIU														
00085012005	Intron	INTRON A INJECTABLE 5MILLIU														
00085053901	Intron	INTRON A INJECTION 5 MILLIU	326.54	317.45	360.76	388.72	429.42	451.27	455.83	450.55	469.34	499.62	509.94	557.09	581.36	599.44
000850668901	Intron	INTRON A INJECTION 5 MILLIU	122.93	133.06	140.99	147.83	156.03									
00085076901	Intron	INTRON A SOL FOR INJ. 25MILLN														
00085095301	Intron	INTRON A SOLUTION 18MILU 3ML	17.66	14.90	11.89	10.63	10.49									
59930160001	Perphenazine	PERPHENAZINE	17.93	82.56	86.37	90.08	90.44									
59930160002	Perphenazine	PERPHENAZINE 16MG														
59930160003	Perphenazine	PERPHENAZINE 16MG	41.96	37.26	29.98	27.75	26.81	30.06	24.91							
59930160004	Perphenazine	PERPHENAZINE 8MG	30.30	27.34	20.45	16.17	16.38	19.36	18.50							
59930160302	Perphenazine	PERPHENAZINE 8MG	24.25	21.60	15.73	14.21	13.80	16.48	14.43							
00085133601	Proventil	PROVENTIL INHALATION SOLUTION														
00085020901	Proventil	PROVENTIL SOLUTION .083MG/M	26.39	25.38	23.01	27.31	26.44	27.24	30.72	34.09	35.85	36.23	35.16	42.72	30.43	4.37
00085180601	Proventil	PROVENTIL SOLUTION .083MG/M	11.72	11.58	9.75	11.92	11.00	11.37	11.78	15.25	16.96	16.58	17.07	7.80		
00085020802	Proventil	PROVENTIL SOLUTION 5MG/M														
00085125901	Temodar	TEMODAR 100MG														
00085125902	Temodar	TEMODAR 100MG														
00085124401	Temodar	TEMODAR 20MG														
00085124402	Temodar	TEMODAR 20MG														
00085125201	Temodar	TEMODAR 250MG														

**Attachment G.4.a: Schering-Plough Annual Average Sales Price**

NDC	Description	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004Q1
00085125202	Temodar	TEMODAR 250MG										5,000.00	4,972.37	4,731.15	5,329.37	5,200.90
00085124801	Temodar	TEMODAR 5MG										24.98	25.00	26.17	29.19	30.57
00085124802	Temodar	TEMODAR 5MG										100.00	100.16	102.27	110.60	119.03

**Attachment G.4.b: Schering-Plough Annual AWPs**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	
59930151504	Albuterol	ALBUTEROL INHALATION SOLUTION	12.50	12.50	13.95	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	
59930164702	Albuterol	ALBUTEROL INHALATION SOLUTION	72.60	72.60	13.95	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	14.99	
59930150006	Albuterol	ALBUTEROL SULFATE INHAL. SOL.	30.25	30.25	72.60	72.60	72.60	72.60	72.60	72.60	72.60	72.60	72.60	72.60	72.60	72.60	
59930150008	Albuterol	ALBUTEROL SULFATE INHAL. SOL.	31.51	31.51	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	
59930151701	Albuterol	ALBUTEROL SULFATE SOLUTION	30.25	30.25	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	
59930151702	Albuterol	ALBUTEROL SULFATE SOLUTION	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	
599301556020	Albuterol	ALBUTEROL SULFATE SOLUTION	180.04	180.04	197.54	203.47	203.47	209.58	209.58	213.77	213.77	213.77	213.77	213.77	213.77	213.77	
00085123501	Intron	INTRON A FOR INJ MULTIDOSE PEN	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	
00085124201	Intron	INTRON A FOR INJ MULTIDOSE PEN	180.04	180.04	197.54	203.47	203.47	209.58	209.58	213.77	213.77	213.77	213.77	213.77	213.77	213.77	
00085125401	Intron	INTRON A FOR INJ MULTIDOSE PEN	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	30.25	
00085116801	Intron	INTRON A INJ 18MLU HSA FREE	180.04	180.04	197.54	203.47	203.47	209.58	209.58	213.77	213.77	213.77	213.77	213.77	213.77	213.77	
00085113301	Intron	INTRON A INJ 25MLU HSA-FREE	282.62	282.62	291.11	296.93	296.93	317.70	317.70	341.59	341.59	341.59	341.59	341.59	341.59	341.59	
00085118401	Intron	INTRON A INJ 3MLU HSA-FREE	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	33.92	
00085118402	Intron	INTRON A INJ 3MLU HSA-FREE	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	203.47	
00085119101	Intron	INTRON A INJ 5MLU HSA-FREE	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	56.52	
00085119102	Intron	INTRON A INJ 5MLU HSA-FREE	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	339.13	
00085117901	Intron	INTRON A INJ PAK10MLU HSA FREE	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	113.04	
00085117902	Intron	INTRON A INJECTABLE 10MLLU	84.79	84.79	95.72	99.55	105.03	109.75	109.75	113.04	113.04	116.44	116.44	116.44	116.44	116.44	116.44
00085057102	Intron	INTRON A INJECTABLE 10MLLU	574.33	574.33	597.30	597.30	597.30	630.15	630.15	630.15	630.15	630.15	630.15	630.15	630.15	630.15	
00085057106	Intron	INTRON A INJECTABLE 10MLLU	204.00	224.70	239.30	248.88	248.88	248.88	248.88	248.88	262.57	262.57	262.57	262.57	262.57	262.57	
0008511001	Intron	INTRON A INJECTABLE 18MLLU	24.48	26.96	28.72	29.87	29.87	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	
00085028502	Intron	INTRON A INJECTABLE 25MLLU	24.48	26.96	28.42	29.87	29.87	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	31.51	
00085064703	Intron	INTRON A INJECTABLE 3MLLU	146.88	161.78	172.30	179.18	179.18	189.04	189.04	189.04	189.04	189.04	189.04	189.04	189.04	189.04	
00085064704	Intron	INTRON A INJECTABLE 3MLLU	44.94	44.94	47.86	49.78	49.78	52.51	52.51	52.51	52.51	52.51	52.51	52.51	52.51	52.51	
00085064705	Intron	INTRON A INJECTABLE 3MLLU	670.06	670.06	696.86	696.86	696.86	735.19	735.19	735.19	735.19	735.19	735.19	735.19	735.19	735.19	
00085012002	Intron	INTRON A INJECTABLE 5MLLU	424.00	449.40	478.61	497.75	525.12	548.75	548.75	565.21	582.17	593.81	635.36	683.16	710.48	783.01	
00085012003	Intron	INTRON A INJECTION 5MLLU	172.30	172.30	179.18	179.18	179.18	179.18	179.18	179.18	179.18	179.18	179.18	179.18	179.18	179.18	
00085012004	Intron	INTRON A SOL FOR INJ 10MLLI	99.55	99.55	99.55	99.55	99.55	199.10	199.10	199.10	199.10	199.10	199.10	199.10	199.10	199.10	
00085012005	Intron	INTRON A SOL FOR INJ 25MLLN	239.30	248.88	248.88	248.88	248.88	262.57	262.57	262.57	262.57	262.57	262.57	262.57	262.57	262.57	
00085092301	Intron	PERphenazine	40.80	40.80	40.80	40.80	40.80	46.00	46.00	46.00	46.00	46.00	46.00	46.00	46.00	46.00	
59930160001	Perphenazine	PERphenazine	90.65	90.65	108.00	108.00	108.00	108.00	108.00	108.00	108.00	108.00	108.00	108.00	108.00	108.00	
59930161001	Perphenazine	PERphenazine 16MG	67.45	67.45	78.00	78.00	78.00	78.00	78.00	78.00	78.00	78.00	78.00	78.00	78.00	78.00	
59930160501	Perphenazine	PERphenazine 8MG	55.50	55.50	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	
59930160502	Perphenazine	PERphenazine 8MG	55.50	55.50	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	65.00	
59930160302	Perphenazine	PERphenazine TABLETS	31.14	35.39	35.39	35.39	35.39	36.98	36.98	40.70	42.33	45.34	45.34	45.34	45.34	45.34	
00085133601	Proventil	PROVENTIL INHALATION SOLUTION	32.40	35.39	35.39	35.39	35.39	38.80	38.80	40.70	43.80	45.34	45.34	45.34	45.34	45.34	
59930160001	Proventil	PROVENTIL SOLUTION .083MG/Ml	13.66	15.53	15.53	15.53	15.53	16.23	17.85	18.56	19.88	21.41	21.41	21.41	21.41	21.41	
00085180601	Proventil	PROVENTIL SOLUTION .083MG/Ml	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	120.00	
00085020901	Proventil	PROVENTIL SOLUTION 5MG/Ml	480.00	480.00	509.36	567.68	567.68	567.68	567.68	567.68	567.68	567.68	567.68	567.68	567.68	567.68	
00085124401	Temodar	TEMODAR 100MG	1,500.00	1,500.00	1,591.81	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	
00085124402	Temodar	TEMODAR 20MG	1,500.00	1,500.00	1,591.81	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	
00085124401	Temodar	TEMODAR 20MG	1,500.00	1,500.00	1,591.81	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	
00085125201	Temodar	TEMODAR 250MG	1,500.00	1,500.00	1,591.81	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	1,774.20	

**Attachment G.4.b: Schering-Plough Annual AWPs**

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00085125202	Temodar	TEMODAR 250MG														
00085124801	Temodar	TEMODAR 5MG														
00085124802	Temodar	TEMODAR 5MG														

**Attachment G.4.c: Schering-Plough Annual Spreads**

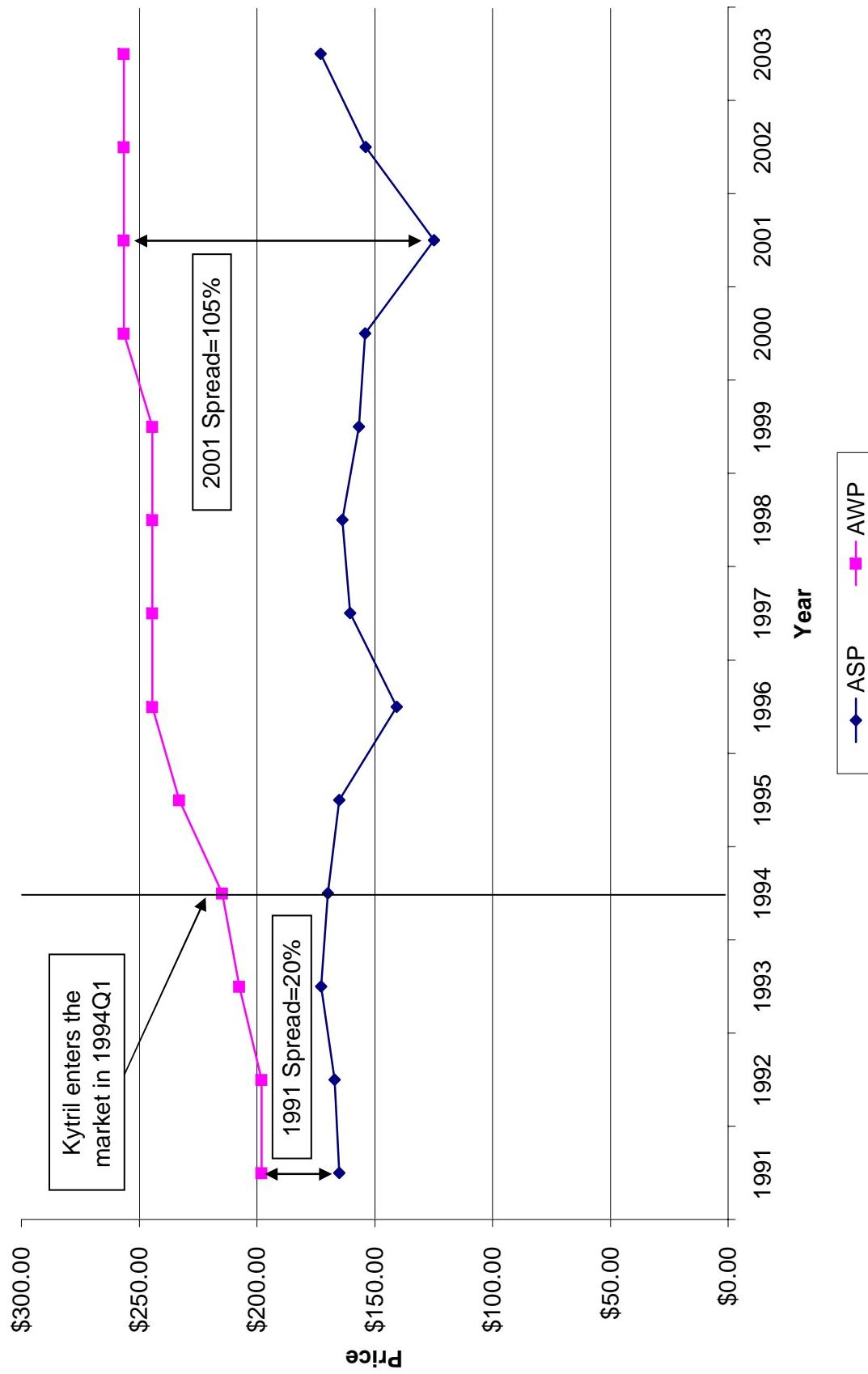
NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004Q1
59930151504	Albuterol	ALBUTEROL INHALATION SOLUTION	107.4%	103.3%	113.1%	147.6%	210.7%	250.7%	297.7%	360.8%	403.3%	420.9%	422.0%	477.2%	524.2%	
59930164702	Albuterol	ALBUTEROL INHALATION SOLUTION	142.0%	139.5%	161.3%	180.6%	302.1%	331.4%	322.9%	451.0%	516.6%	580.6%	651.4%	698.9%	867.3%	1052.8%
59930150006	Albuterol	ALBUTEROL SULFATE INHAL. SOL.	121.3%	135.3%	186.9%	247.1%	321.0%	370.2%	409.1%	520.7%	548.2%	651.4%	698.9%	867.3%	1052.8%	
59930150008	Albuterol	ALBUTEROL SULFATE INHAL. SOL.														
59930151701	Albuterol	ALBUTEROL SULFATE SOLUTION														
59930151702	Albuterol	ALBUTEROL SULFATE SOLUTION														
599301556020	Albuterol	ALBUTEROL SULFATE SOLUTION														
00085123501	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085124201	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085125401	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085116801	Intron	INTRON A INJ 18MIU HSA FREE														
00085113301	Intron	INTRON A INJ 25MIU HSA FREE														
00085118401	Intron	INTRON A INJ 3MIU HSA FREE														
00085118402	Intron	INTRON A INJ 3MIU HSA FREE														
00085119101	Intron	INTRON A INJ 5MIU HSA FREE														
00085119102	Intron	INTRON A INJ 5MIU HSA FREE														
00085117901	Intron	INTRON A INJ PAK10MIU HSA FREE														
00085117902	Intron	INTRON A INJECTABLE 10MILLN IU	33.4%	34.8%	27.6%	25.2%	23.4%	22.6%	21.4%	20.0%	21.0%	24.3%	21.5%	24.7%	27.7%	29.5%
00085057102	Intron	INTRON A INJECTABLE 10MILLN IU														
00085057106	Intron	INTRON A INJECTABLE 10MILLN IU														
00085111001	Intron	INTRON A INJECTABLE 18MILLN IU														
00085028902	Intron	INTRON A INJECTABLE 25MILLN IU														
00085064703	Intron	INTRON A INJECTABLE 3MILLN IU	18.9%	21.5%	21.2%	20.3%	17.4%	17.4%	17.4%	17.4%	17.4%	17.4%	17.4%	20.4%	23.4%	27.9%
00085064704	Intron	INTRON A INJECTABLE 3MILLN IU														
00085064705	Intron	INTRON A INJECTABLE 3MILLN IU														
00085012002	Intron	INTRON A INJECTABLE 5 MILLN IU	44.0%	21.7%	22.0%	20.4%	20.4%	17.4%	17.4%	20.1%	16.6%	18.5%	64.1%	22.6%	28.2%	
00085012003	Intron	INTRON A INJECTABLE 5 MILLN IU	50.4%	36.8%	29.9%	27.3%	27.3%	17.7%	20.2%	20.2%	17.7%	17.7%	17.7%	20.2%		
00085012004	Intron	INTRON A INJECTABLE 5 MILLN IU														
00085012005	Intron	INTRON A INJECTABLE 5 MILLN IU														
00085053901	Intron	INTRON A INJECTABLE 50MILLN IU	29.8%	41.6%	32.7%	28.0%	22.3%	16.4%	22.3%	22.3%	29.2%	26.5%	27.2%	34.0%	27.5%	35.8%
00085068901	Intron	INTRON A INJECTION 18 MIU														
00085092301	Intron	INTRON A SOL FOR INJ 10 MILLI														
00085076901	Intron	INTRON A SOL. FOR INJ. 25MILLIN														
00085095301	Intron	INTRON A SOLUTION 18MIU 3ML														
59930160001	Perphenazine	PERPHENAZINE														
59930160002	Perphenazine	PERPHENAZINE 16MG														
59930160003	Perphenazine	PERPHENAZINE 8MG														
59930160004	Perphenazine	PERPHENAZINE 8MG														
59930160005	Perphenazine	PERPHENAZINE TABLETS														
59930160302	Perphenazine	PERPHENAZINE TABLETS														
00085133601	Proventil	PROVENTIL INHALATION SOLUTION	18.0%	39.4%	53.8%	29.6%	33.9%	32.5%	24.2%	26.5%	25.1%	38.9%	20.0%	77.0%	1169.7%	
00085020901	Proventil	PROVENTIL SOLUTION .083MG/ML														
00085180601	Proventil	PROVENTIL SOLUTION .083MG/ML														
00085020802	Proventil	PROVENTIL SOLUTION 5MG/ML	16.5%	34.1%	59.4%	30.3%	41.2%	42.8%	51.5%	21.7%	17.2%	19.9%	25.5%	188.5%	22.7%	24.9%
00085125901	Temodar	TEMODAR 100MG														
00085125902	Temodar	TEMODAR 100MG														
00085124401	Temodar	TEMODAR 20MG														
00085124402	Temodar	TEMODAR 20MG														
00085125201	Temodar	TEMODAR 250MG														

**Attachment G.4.c: Schering-Plough Annual Spreads**

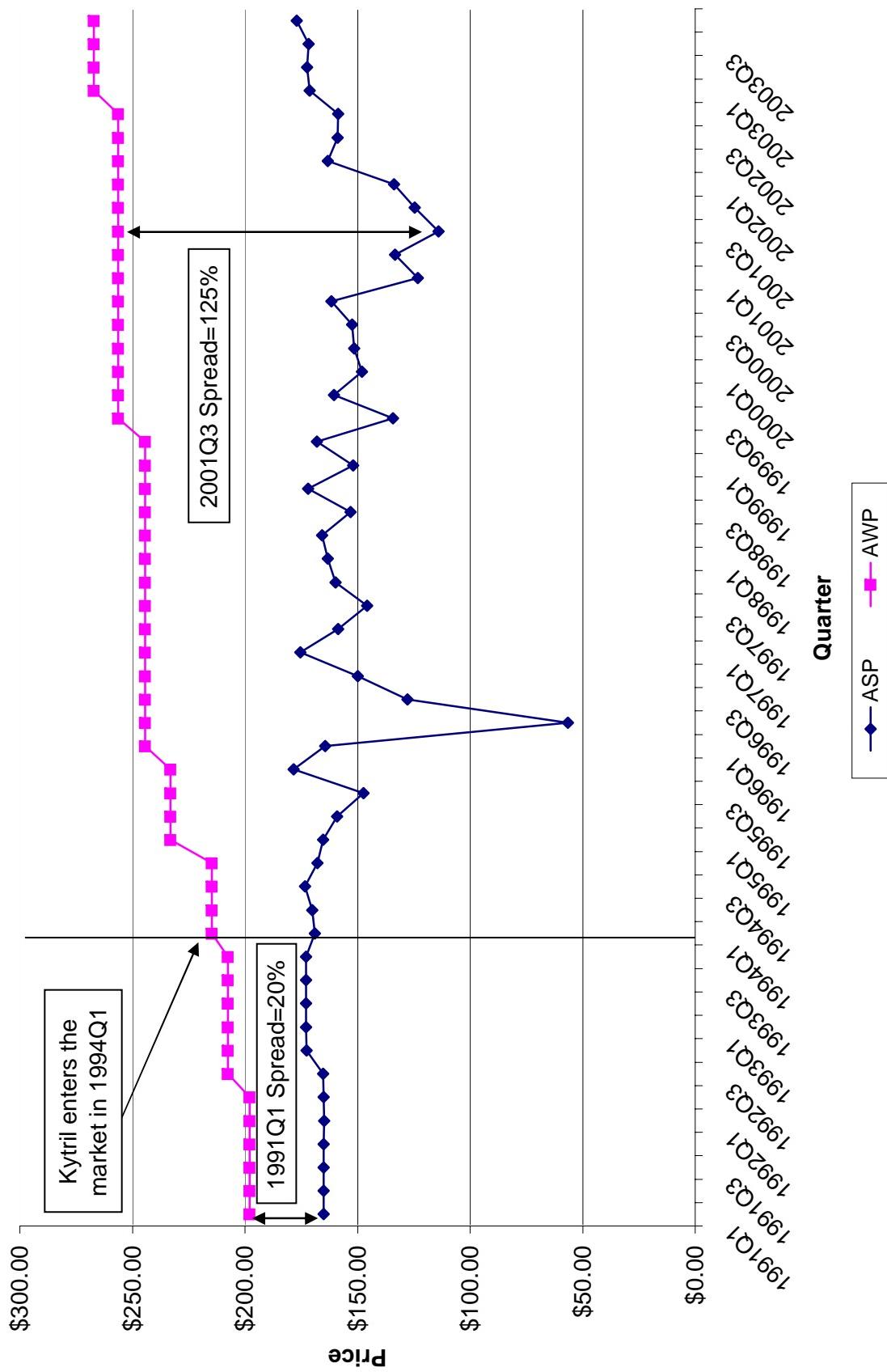
<b>NDC</b>	<b>Drug</b>	<b>Description</b>	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004Q1
00085125202	Temodar	TEMODAR 250MG									20.0%	20.7%	34.6%	33.2%	48.9%	
00085124801	Temodar	TEMODAR 5MG									20.1%	20.0%	21.7%	21.5%	26.6%	
00085124802	Temodar	TEMODAR 5MG									20.0%	19.8%	24.5%	28.3%	30.1%	

**Attachment H: Yardstick Candidates**

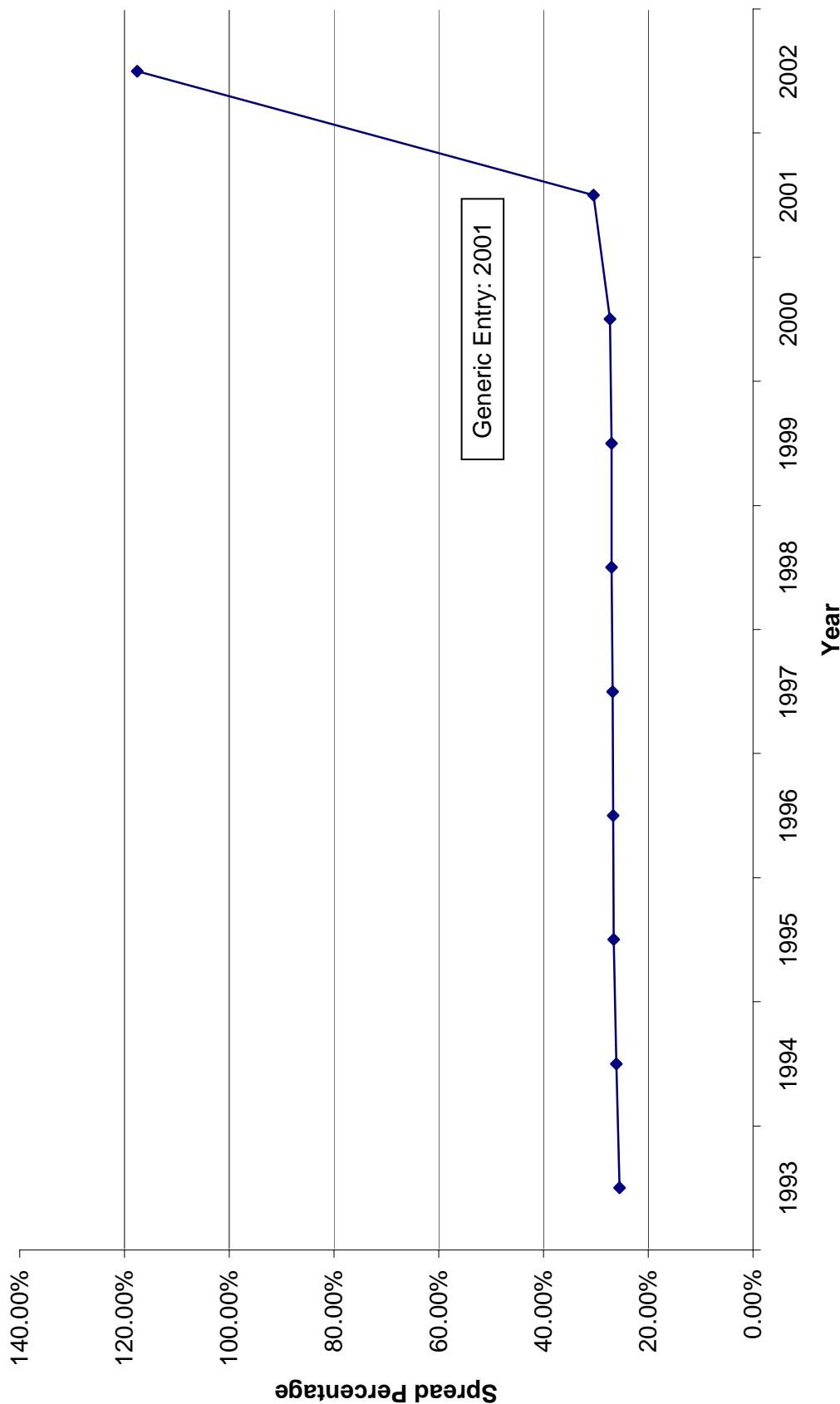
**Attachment H.1.a: Zofran Annual ASP vs. AWP, 1991-2003 (NDC 00173-0442-00)**



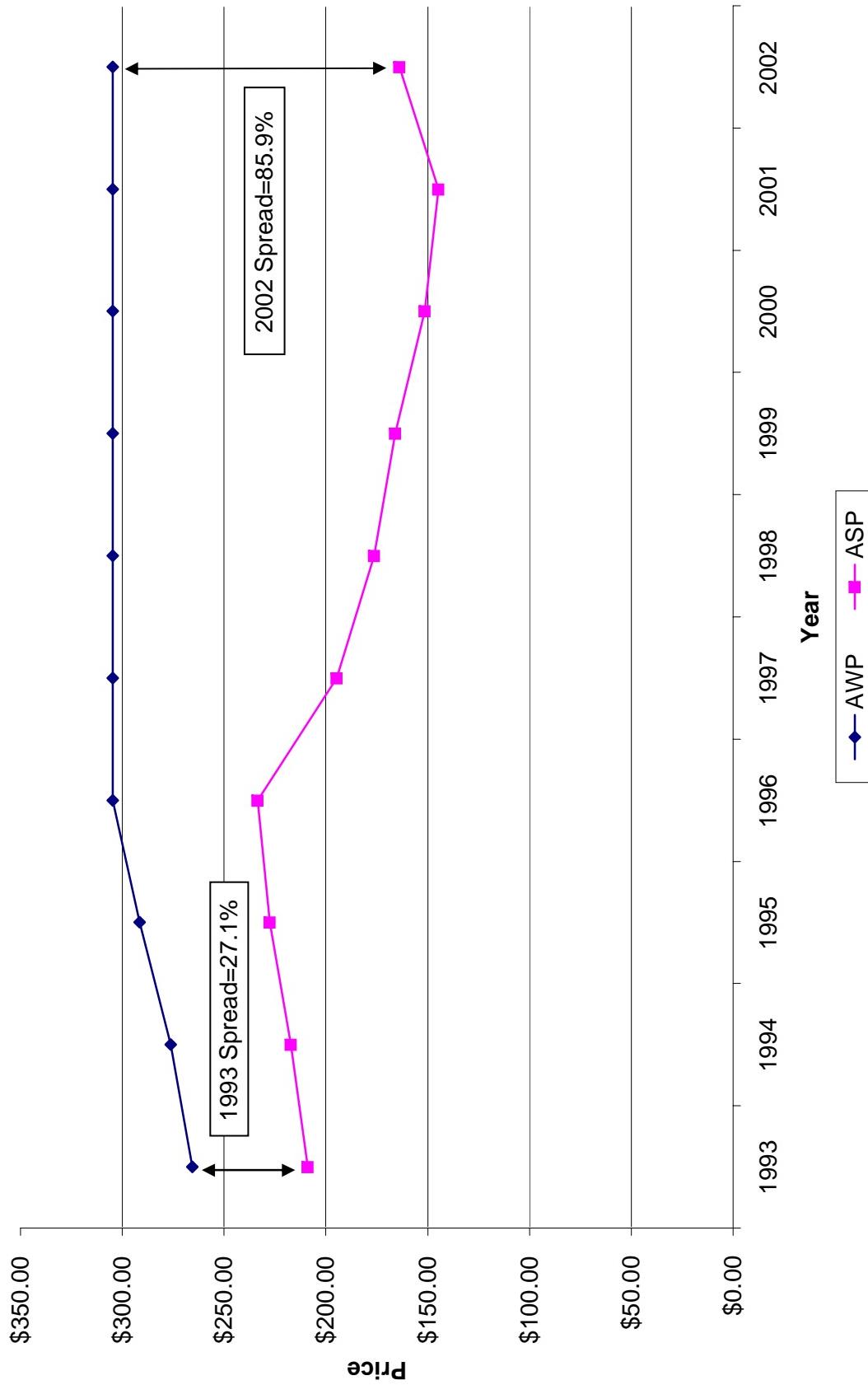
Direct Testimony of Raymond S. Hartman

**Attachment H.1.b: Zofran Quarterly ASP vs. AWP, 1991-2003 (NDC 00173-0442-00)**

**Attachment H.2: Taxol Spread Percentage,  
Unit-weighted Average Across All NDCs, 1993-2002**



**Attachment H.3: Blenoxane Annual ASP vs. AWP, 1993-2002 (NDC 00015-3010-20)**



**Attachment I: Liability Threshold for Class 3 by Defendant**

**Attachment I.1: AstraZeneca Drugs Subject to Liability**

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

<b>NDC</b>	<b>Drug</b>	<b>Description</b>	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot			X	X	X	X	X	X	X	X	X	X	X	
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot														

### Attachment I.2: Bristol-Myers Squibb Drugs Subject to Liability

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015301020	Blenoxane	BLENOXANE INJ 15 UNIT VL				X	X	X	X	X	X	X
00015301026	Blenoxane	BLENOXANE INJ 15 UNIT VHA										
00015306301	Blenoxane	BLENOXANE INJ 30 UNIT VL										
00015306326	Blenoxane	BLENOXANE INJ 30 UNIT VHA										
00015505001	Cytoxan	CYTOKAN FOR INJ 100 MG										
000155050041	Cytoxan	CYTOKAN INJ 100MG										
00015505141	Cytoxan	CYTOKAN INJ 200MG										
00015505241	Cytoxan	CYTOKAN INJ 1X500MG VIAL										
00015505301	Cytoxan	CYTOKAN TABS 50MG										
00015505302	Cytoxan	CYTOKAN TABLETS 50MG										
00015505303	Cytoxan	CYTOKAN TABLETS 50 MG										
00015505348	Cytoxan	CYTOKAN TABS 50MG										
00015505401	Cytoxan	CYTOKAN TABS 25MG										
00015505641	Cytoxan	CYTOKAN PINJ 1X1G VIAL										
00015505641	Cytoxan	CYTOKAN INJ 1X25M VIAL										
000155053910	Cytoxan	CYTOKAN 100MG LYOPH W/CYT										
000155053941	Cytoxan	CYTOKAN LYOPHILIZED 100MG										
000155054611	Cytoxan	CYTOKAN 200MG LYOPH W/CYT										
000155054641	Cytoxan	CYTOKAN LYOPHILIZED 200MG										
000155054710	Cytoxan	CYTOKAN 500MG LYOPH W/CYT										
000155054712	Cytoxan	CYTOKAN LYO 500MG VL VHA										
000155054741	Cytoxan	CYTOKAN LYOPH 500MG										
000155054810	Cytoxan	CYTOKAN 1GM LYOPH W/CYT/TOG										
000155054812	Cytoxan	CYTOKAN 1G 6/50ML VHA+										
000155054841	Cytoxan	CYTOKAN LYOPHILIZED 1GM										
000155054910	Cytoxan	CYTOKAN 2GM LYOPH W/CYT/TOG										
000155054912	Cytoxan	CYTOKAN 2G 6/100ML VHA+										
000155054941	Cytoxan	CYTOKAN LYOPHILIZED 2GM										
000155204020	Etopophos	ETOPOPHOS 100MG VIAL										
00015521310	Paraplatin	PARAPLATIN 50MG W/CYTO										
00015521329	Paraplatin	PARAPLATIN 10X5ML VHA+										
00015521330	Paraplatin	PARAPLATIN 50MG LYOPHILIZ										
00015521410	Paraplatin	PARAPLATIN 150MG LYOPH CY										
00015521429	Paraplatin	PARAPLATIN 10X15ML VHA+										
00015521430	Paraplatin	PARAPLATIN 1X150MG LYO VL										
00015521510	Paraplatin	PARAPLATIN 450MG VL W/CYT										
00015521529	Paraplatin	PARAPLATIN 10X45ML VHA+										
00015521530	Paraplatin	PARAPLATIN 1X450MG LYO VL										
00015535122	Rubex	RUBEX 10MG LYOPHILIZED										
00015535124	Rubex	RUBEX 10MG IMMUNEX LABEL										
00015535222	Rubex	RUBEX 50MG LYOPHILIZED										
00015535224	Rubex	RUBEX 50MG IMMUNEX LABEL										
0001553522	Rubex	RUBEX 100 MG LYOPHILIZED										
0001553524	Rubex	RUBEX 100MG IMMUNEX LABEL										
00015545620	Taxol	TAXOL 30MG CONC FOR INJ										
00015547520	Taxol	TAXOL 30MG SEM-SYN VIAL										
00015547530	Taxol	TAXOL 30MG INJ MULTIDOSE										
00015547520	Taxol	TAXOL 100MG/16.7ML VHA+ L										
00015547627	Taxol	TAXOL 100MG SEM-SYN VIAL										

**Attachment I.2: Bristol-Myers Squibb Drugs Subject to Liability**

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347630	Taxol	TAXOL 100MG INJ MULTIDOSE									X	
00015347911	Taxol	TAXOL 300MG/50ML VIAL										
00015306120	Vepesid	VEPESID 500MG	X	X	X	X	X	X	X			
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA										
00015306220	Vepesid	VEPESID 1GM/50ML	X	X	X	X	X	X	X			
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+										
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML										
00015309145	Vepesid	VEPESID 50MG CAPSULES										
00015309510	Vepesid	VEPESID 100MG VIAL W/CYTO										
00015309520	Vepesid	VEPESID INJ 100MG/5ML										
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO										

**Attachment I.3: Johnson & Johnson Drugs Subject to Liability**

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG													
00062740103	Procrit	PROCRIT 1000U/ML AMG													
00062740201	Procrit	PROCRIT 2000U/ML AMG													
00062740501	Procrit	PROCRIT 3000U/ML AMG													
59676030201	Procrit	PROCRIT 2000 U/ML 6'S													
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTIO													
59676030301	Procrit	PROCRIT 3000 U/ML 6'S													
59676030302	Procrit	PROCRIT 3000 U/ML 25S													
59676030401	Procrit	PROCRIT 4000 U/ML 6'S													
59676030402	Procrit	PROCRIT 4000 U/ML 25S													
59676031001	Procrit	PROCRIT 10000 U/ML 6'S													
59676031002	Procrit	PROCRIT 10000 U/ML 25S													
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS													
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML													
59676034001	Procrit	PROCRIT 40000 U/ML 4'S													
57894003001	Remicade	C168J REMICADE 1PC/K US PD	X	X											

#### Attachment I.4: Schering-Plough Drugs Subject to Liability

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
59930151504	Albuterol	ALBUTEROL INHALATION SOLUTION			X	X	X	X	X	X	X	X	X	X	X	X
59930164702	Albuterol	ALBUTEROL INHALATION SOLUTION			X	X	X	X	X	X	X	X	X	X	X	X
59930150006	Albuterol	ALBUTEROL SULFATE INHAL. SOL.			X	X	X	X	X	X	X	X	X	X	X	X
59930150008	Albuterol	ALBUTEROL SULFATE INHAL. SOL.			X	X	X	X	X	X	X	X	X	X	X	X
59930151701	Albuterol	ALBUTEROL SULFATE SOLUTION														
59930151702	Albuterol	ALBUTEROL SULFATE SOLUTION														
59930155620	Albuterol	ALBUTEROL SULFATE SOLUTION														
00085123501	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085124201	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085125401	Intron	INTRON A FOR INJ MULTIDOSE PEN														
00085116801	Intron	INTRON A INJ 18MLU HSA FREE														
00085113301	Intron	INTRON A INJ 25MLU HSA FREE														
00085118401	Intron	INTRON A INJ 3MLU HSA FREE														
00085118402	Intron	INTRON A INJ 3MLU HSA FREE														
00085119101	Intron	INTRON A INJ 5MLU HSA FREE														
00085119102	Intron	INTRON A INJ 5MLU HSA FREE														
00085117901	Intron	INTRON A INJ PAK 10MLU HSA FREE														
00085117902	Intron	INTRON A INJ PAK 10MLU HSA FREE														
00085057102	Intron	INTRON A INJECTABLE 10MLLN IU	X	X	X	X	X	X	X	X	X	X	X	X	X	X
00085057106	Intron	INTRON A INJECTABLE 10MLLN IU														
00085111001	Intron	INTRON A INJECTABLE 18MLLN IU														
00085028502	Intron	INTRON A INJECTABLE 25MLLN IU														
00085064703	Intron	INTRON A INJECTABLE 3MLLN IU														
00085064704	Intron	INTRON A INJECTABLE 3MLLN IU														
00085064705	Intron	INTRON A INJECTABLE 3MLLN IU														
00085012002	Intron	INTRON A INJECTABLE 5MLLN IU	X	X	X	X	X	X	X	X	X	X	X	X	X	X
00085012003	Intron	INTRON A INJECTABLE 5MLLN IU														
00085012004	Intron	INTRON A INJECTABLE 5MLLN IU														
00085012005	Intron	INTRON A INJECTABLE 5MLLN IU														
00085053901	Intron	INTRON A INJECTABLE 50MLLN IU	X	X	X	X	X	X	X	X	X	X	X	X	X	X
00085068901	Intron	INTRON A INJECTION 1.8 MLU														
00085092301	Intron	INTRON A SOL FOR INJ 10 MILLN														
00085076901	Intron	INTRON A SOL. FOR INJ 25MILLN														
00085095301	Intron	INTRON A SOLUTION 18MLU 3ML														
59930160001	Perphenazine	PERPHENAZINE														
59930160002	Perphenazine	PERPHENAZINE														
59930161601	Perphenazine	PERPHENAZINE 16MG														
59930160501	Perphenazine	PERPHENAZINE 8MG														
59930160502	Perphenazine	PERPHENAZINE 8MG														
59930160301	Perphenazine	PERPHENAZINE TABLETS														
59930160302	Perphenazine	PERPHENAZINE TABLETS														
00085133601	Proventil	PROVENTIL INHALATION SOLUTION														
00085020901	Proventil	PROVENTIL SOLUTION .083MG/ML														
00085180601	Proventil	PROVENTIL SOLUTION .083MG/ML														
00085020802	Proventil	PROVENTIL SOLUTION 5MG/ML														
00085125901	Temodar	TEMODAR 100MG														
00085125902	Temodar	TEMODAR 20MG														
00085124401	Temodar	TEMODAR 20MG														
00085124402	Temodar	TEMODAR 250MG														
00085125201	Temodar	TEMODAR 250MG														

**Attachment I.4: Schering-Plough Drugs Subject to Liability**

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00085125202	Temodar	TEMODAR 250MG											X	X	X	
00085124801	Temodar	TEMODAR 5MG														
00085124802	Temodar	TEMODAR 5MG											X	X	X	X

**Attachment J: Summary of Damages by Defendant**

**Attachment J.1.a: Summary of Massachusetts AstraZeneca Damages by Class and by Drug****Class 2: Medicare Damages to Massachusetts Third-Party Payors**

<b>Drug</b>	<b>1991</b>	<b>1992</b>	<b>1993</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>Thru 10-06</b>	<b>Total</b>	<b>Total, Including Pre- Judgment Interest</b>
Zoledex	12,124	19,490	22,338	46,499	80,795	143,875	238,994	479,102	500,180	538,547	631,172	647,331	689,388	731,445	0	0	4,781,279	6,990,393
Total	12,124	19,490	22,338	46,499	80,795	143,875	238,994	479,102	500,180	538,547	631,172	647,331	689,388	731,445	0	0	4,781,279	6,990,393

**Class 3: Non-Medicare Damages to Massachusetts Consumers and Third-Party Payors**

<b>Drug</b>	<b>1991</b>	<b>1992</b>	<b>1993</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>Thru 10-06</b>	<b>Total</b>	<b>Total, Including Pre- Judgment Interest</b>
Zoledex	0	0	0	6,230	52,227	106,414	262,428	755,564	804,701	858,145	1,008,700	1,033,962	1,103,562	1,173,162	1,242,761	1,093,634	9,501,489	11,255,956
Total	0	0	0	6,230	52,227	106,414	262,428	755,564	804,701	858,145	1,008,700	1,033,962	1,103,562	1,173,162	1,242,761	1,093,634	9,501,489	11,255,956

**Attachment J.1.b: Summary of National AstraZeneca Damages by Class and by Drug****Class 2: Medicare Damages to National Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thru 10-06</u>	<u>Total</u>	<u>Total, Including Pre- Judgment Interest</u>	
Zoledex	458,664	737,323	845,084	1,759,125	3,056,597	5,443,000	9,041,502	18,125,133	18,922,543	20,374,007	23,878,143	24,489,460	26,080,542	27,671,624	0	0	0	180,882,758	264,456,743
Total	458,664	737,323	845,084	1,759,125	3,056,597	5,443,000	9,041,502	18,125,133	18,922,543	20,374,007	23,878,143	24,489,460	26,080,542	27,671,624	0	0	0	180,882,758	264,456,743

**Class 3: Non-Medicare Damages to National Consumers and Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thru 10-06</u>	<u>Total</u>	<u>Total, Including Pre- Judgment Interest</u>
Zoledex	0	0	0	235,680	1,975,807	4,025,790	9,928,042	28,584,074	30,443,009	32,464,864	38,160,589	39,116,301	41,749,358	44,382,415	47,015,472	41,373,774	359,455,174	425,829,199
Total	0	0	0	235,680	1,975,807	4,025,790	9,928,042	28,584,074	30,443,009	32,464,864	38,160,589	39,116,301	41,749,358	44,382,415	47,015,472	41,373,774	359,455,174	425,829,199

**Attachment J.2.a: Summary of Massachusetts Bristol-Myers Squibb Damages by Class and by Drug****Class 2: Medicare Damages to Massachusetts Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thru 10-06</u>	<u>Total</u>	<u>Total, Including Pre- Judgment Interest</u>
Blenoxane	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cytoxan	304	4,022	7,741	10,908	14,065	17,587	22,617	22,682	24,875	17,148	13,743	15,470	15,454	0	0	202,071	341,403	
Etopophos	0	0	0	0	0	419	1,231	813	263	207	144	141	100	59	0	0	3,376	5,799
Paraplatin	16,437	31,906	47,375	43,129	61,704	72,122	75,516	80,378	99,123	121,588	134,766	186,597	202,066	217,535	0	0	1,390,244	2,161,431
Rubex	328	393	457	521	1,888	1,829	715	355	457	305	355	54	288	288	0	0	8,242	16,157
Taxol	0	0	42,450	72,992	119,925	158,095	187,358	179,974	214,528	234,303	115,934	91,372	19,907	0	0	0	1,436,838	2,489,364
Vepesid	58,227	58,227	87,340	39,861	52,306	67,797	53,436	36,137	35,881	42,588	23,888	21,242	10,589	0	0	587,498	1,212,407	
Total	75,296	94,548	185,364	167,412	249,898	317,849	340,873	320,339	374,974	416,290	288,830	314,876	248,384	233,336	0	0	3,628,269	6,226,562

**Class 3: Non-Medicare Damages to Massachusetts Consumers and Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thru 10-06</u>	<u>Total</u>	<u>Total, Including Pre- Judgment Interest</u>
Blenoxane	0	0	0	0	0	0	2,471	0	0	0	0	0	0	0	0	0	2,471	3,755
Cytoxan	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Etopophos	0	0	0	0	0	0	491	0	0	0	0	0	0	0	0	0	491	746
Paraplatin	0	0	0	0	0	0	0	28,388	2,493	303	0	9,594	402,284	402,284	0	0	1,247,630	1,426,074
Rubex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Taxol	0	0	0	0	0	0	0	0	46	0	0	183,454	0	0	0	0	183,500	226,191
Vepesid	0	0	8,096	63,710	0	0	0	0	0	0	0	0	0	0	0	0	71,807	119,187
Total	0	0	8,096	63,710	0	2,962	28,388	2,539	303	0	193,048	402,284	402,284	0	0	0	1,505,899	1,775,954

**Attachment J.2.b: Summary of National Bristol-Myers Squibb Damages by Class and by Drug****Class 2: Medicare Damages to National Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	10-06	Thru	Total	Total, Including Pre-Judgment Interest
Blenoxane	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cytoxan	11,484	152,177	292,870	412,651	532,113	665,349	855,640	858,086	941,045	648,751	519,909	585,264	584,642	584,642	0	0	7,644,622	12,915,783	
Etopophos	0	0	0	0	0	15,855	46,560	30,753	9,958	7,824	5,459	5,317	3,771	2,224	0	0	127,720	219,381	
Paraplatin	621,847	1,207,065	1,792,282	1,631,646	2,334,364	2,728,498	2,856,870	3,040,812	3,749,963	4,599,838	5,098,397	7,059,240	7,644,457	8,229,675	0	0	52,594,964	81,770,073	
Rubex	12,415	14,851	17,287	19,724	71,804	69,182	27,032	13,423	11,538	17,270	13,436	2,033	10,913	10,913	0	0	311,821	611,253	
Taxol	0	0	1,605,937	2,761,402	4,536,923	5,980,947	7,088,040	6,808,691	8,115,906	8,864,014	4,385,961	3,456,751	753,119	0	0	0	54,357,691	94,176,285	
Vepesid	2,202,803	2,202,803	3,304,205	1,507,998	1,978,818	2,564,869	2,021,572	1,367,116	1,357,418	1,611,151	903,702	803,611	399,842	0	0	0	22,225,910	45,867,132	
Total	2,848,550	3,576,896	7,012,581	6,333,421	9,454,022	12,024,699	12,895,713	12,118,882	14,185,827	15,748,848	10,926,865	11,912,216	9,396,743	8,827,453	0	0	137,262,718	235,559,906	

**Class 3: Non-Medicare Damages to National Consumers and Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	10-06	Thru	Total	Total, Including Pre-Judgment Interest
Blenoxane	0	0	0	0	0	93,493	0	0	0	0	0	0	0	0	0	0	0	93,463	142,046
Cytoxan	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Etopophos	0	0	0	0	0	18,577	0	0	0	0	0	0	0	0	0	0	18,577	28,224	
Paraplatin	0	0	0	0	0	0	1,073,971	94,321	11,462	0	362,945	15,218,982	15,218,982	0	0	0	47,199,646	53,950,466	
Rubex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Taxol	0	0	0	0	0	0	0	0	1,732	1	0	6,940,347	0	0	0	0	6,942,080	8,557,142	
Vepesid	0	0	306,293	2,410,256	0	0	0	0	0	0	0	0	0	0	0	0	2,716,549	4,509,091	
Total	0	0	306,293	2,410,256	0	112,070	1,073,971	96,053	11,463	0	7,303,292	15,218,982	15,218,982	0	0	0	56,970,345	67,186,909	

**Attachment J.3.a: Summary of Johnson & Johnson Massachusetts Damages by Class and by Drug****Class 2: Medicare Damages to Massachusetts Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>Total</u>	<u>Total, Including Pre-Judgment Interest</u>
Procrit	14,402	24,535	35,488	50,536	72,505	108,020	133,311	179,716	299,193	416,187	526,134	636,739	582,752	0	0	3,662,269	5,283,923	
Remicade	0	0	0	0	0	0	0	5,941	19,095	58,337	156,715	261,870	315,105	400,694	0	0	1,217,756	1,536,951
Total	14,402	24,535	35,488	50,536	72,505	108,020	133,311	185,657	318,287	474,524	682,849	898,609	897,857	983,446	0	0	4,880,025	6,820,873

**Class 3: Non-Medicare Damages to Massachusetts Consumers and Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>Total</u>	<u>Total, Including Pre-Judgment Interest</u>
Procrit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Remicade	0	0	0	0	0	0	0	0	0	27,868	0	208,923	0	0	0	0	0	294,868
Total	0	0	0	0	0	0	0	0	0	27,868	0	208,923	0	0	0	0	0	294,868

**Attachment J.3.b: Summary of Johnson & Johnson National Damages by Class and by Drug****Class 2: Medicare Damages to National Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thru 10-06</u>	<u>Total</u>	<u>Total, Including Pre-Judgment Interest</u>	
Procrit	544,862	928,186	1,342,546	1,911,867	2,742,954	4,086,556	5,043,338	6,798,930	11,318,894	15,744,952	19,904,406	24,088,749	22,046,360	0	0	138,548,961	199,898,491		
Remicade	0	0	0	0	0	0	224,743	722,380	2,206,976	5,928,763	9,906,925	11,920,873	15,158,838	0	0	46,069,498	58,145,083		
Total	544,862	928,186	1,342,546	1,911,867	2,742,954	4,086,556	5,043,338	7,023,673	12,041,275	17,951,928	25,833,169	33,995,674	33,967,233	37,205,198	0	0	184,618,460	258,043,574	

**Class 3: Non-Medicare Damages to National Consumers and Third-Party Payors**

<u>Drug</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>	<u>2005</u>	<u>Thru 10-06</u>	<u>Total</u>	<u>Total, Including Pre-Judgment Interest</u>
Procrit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Remicade	0	0	0	0	0	0	0	0	0	1,054,302	0	7,903,861	0	0	0	0	8,958,163	11,155,281
Total	0	0	0	0	0	0	0	0	0	1,054,302	0	7,903,861	0	0	0	0	8,958,163	11,155,281

**Attachment J.4.a: Summary of Massachusetts Schering-Plough Damages by Class and by Drug**

**Class 2: Medicare Damages to Massachusetts Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre-Judgment Interest
Albuterol	0	0	6,965	72,887	146,444	280,058	413,809	442,529	530,643	546,178	440,665	394,613	254,932	157,850	0	0	3,687,573	5,866,731
Intron	6,182	7,609	6,460	5,595	3,950	9,434	11,199	8,815	7,063	9,491	10,378	12,862	13,921	15,398	0	0	128,336	219,335
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	23,360	64,580	53,147	17,380	13,872	8,463	1,753	0	0	0	0	0	0	0	0	0	182,627	448,135
Temodar	0	0	0	0	0	0	0	1,138	5,741	10,918	17,996	18,837	23,202	0	0	0	77,832	98,032
Total	29,542	72,189	66,571	95,862	164,247	297,955	426,762	451,343	538,845	561,410	461,961	425,543	287,690	196,450	0	0	4,076,368	6,633,233

**Class 3: Non-Medicare Damages to Massachusetts Consumers and Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre-Judgment Interest
Albuterol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Intron	18,383	42,179	12,265	1,129	0	185	0	0	0	0	28,863	957	42,180	39,833	27,657	23,047	236,680	313,176
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	0	35,352	0	0	0	0	0	0	0	0	0	0	0	0	0	0	35,352	63,492
Temodar	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	18,383	77,531	12,265	1,129	0	185	0	0	0	0	28,863	957	42,180	39,833	27,657	23,047	272,032	376,668

### Attachment J.4.b: Summary of National Schering-Plough Damages by Class and by Drug

#### **Class 2: Medicare Damages to National Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre- Judgment Interest
Albuterol	0	0	263,480	2,757,419	5,540,197	10,594,987	15,655,005	16,741,505	20,074,992	20,662,707	16,671,008	14,928,801	9,644,456	5,971,706	0	0	139,506,263	221,946,986
Intron	233,875	287,853	244,385	211,659	148,680	356,893	423,685	333,472	267,217	359,050	392,620	486,592	526,648	582,514	0	0	4,855,142	8,297,754
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	883,737	2,443,160	2,010,610	657,511	524,815	320,184	66,320	0	0	0	0	2,715	0	0	0	0	6,909,052	16,953,598
Temodar	0	0	0	0	0	0	0	0	0	43,068	217,202	413,036	680,809	712,623	877,763	0	0	2,944,499
Total	1,117,612	2,731,013	2,518,475	3,626,589	6,213,692	11,272,064	16,145,010	17,074,977	20,385,277	21,238,958	17,476,664	16,098,917	10,883,727	7,431,983	0	0	154,214,957	250,944,878

#### **Class 3: Non-Medicare Damages to National Consumers and Third-Party Payors**

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Thru 10-06	Total	Total, Including Pre- Judgment Interest
Albuterol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Intron	695,466	1,595,693	464,022	42,730	0	7,007	0	0	0	0	1,091,927	36,214	1,595,743	1,506,936	1,046,298	871,915	8,953,949	11,847,905
Perphenazine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Proventil	0	1,337,408	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1,337,408	2,401,999
Temodar	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	695,466	2,933,101	464,022	42,730	0	7,007	0	0	0	0	1,091,927	36,214	1,595,743	1,506,936	1,046,298	871,915	10,291,358	14,249,904

**Attachment J.5.a: NAMCS Data and Other Adjustments**

Drug Name	Data	NAMCS Data Payment Categories									
		Blank (0)	Private Insurance (1)	Medicare (2)	Medicaid (3)	Worker's Comp (4)	Self-Pay (5)	No Charge (6)	Other (7)	Unknown (8)	Other Gov. (10)
<b>AstraZeneca</b>											
Zoledex	NDTI	0.00%	20.18%	74.24%	1.28%	0.00%	0.00%	0.00%	0.31%	2.53%	1.46% 100.00%
<b>Bristol-Myers Squibb</b>											
Blenoxane	NAMCS	0.00%	83.02%	0.00%	7.96%	0.00%	0.00%	0.00%	3.87%	5.16%	0.00% 100.01%
Cytoxan	NAMCS	0.20%	57.26%	30.45%	1.72%	0.38%	1.69%	0.04%	4.55%	3.71%	0.00% 100.00%
Etoposide	NAMCS	0.00%	46.92%	42.97%	4.34%	0.00%	0.00%	0.00%	0.00%	5.77%	0.00% 100.00%
Paraplatin	NAMCS	0.00%	42.51%	34.38%	9.61%	0.00%	0.00%	0.00%	6.27%	7.24%	0.00% 100.01%
Rubex	NAMCS	0.00%	73.56%	26.44%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00% 100.00%
Taxol	NAMCS	0.00%	55.03%	29.54%	4.78%	0.00%	0.00%	0.87%	9.78%	9.78%	0.00% 100.00%
Vepesid	NAMCS	0.00%	46.92%	42.97%	4.34%	0.00%	0.00%	0.00%	0.00%	5.77%	0.00% 100.00%
<b>Johnson &amp; Johnson</b>											
Procit	NDTI	0.00%	39.70%	48.75%	4.05%	0.00%	0.00%	0.00%	0.87%	4.41%	2.22% 100.00%
Remicade	NDTI	0.00%	61.16%	23.36%	5.12%	0.00%	0.00%	0.00%	1.21%	5.30%	3.84% 100.00%
<b>Schering-Plough</b>											
albuterol	N/A**										
Intron A	NDTI	0.00%	62.01%	20.40%	7.39%	0.00%	0.00%	0.00%	0.62%	5.42%	4.15% 100.00%
perphenazine	NDTI	0.00%	23.55%	42.49%	5.30%	0.00%	0.00%	0.00%	5.52%	22.32%	0.82% 100.00%
Proventil	N/A**										
Temodar	NDTI	0.00%	65.16%	16.88%	11.68%	0.00%	0.00%	0.00%	1.19%	2.31%	2.77% 100.00%

Notes:

\*\* Final class percentages are derived from Medicaid percentage (from CMS data) that is excluded and a remaining 75/25 split between Medicare and non-Medicare.

**Attachment J.5.a: NAMICS Data and Other Adjustments**

Drug Name	DOD %	Calculation of Market Segments			16	17	18	19	20	21	22
		Private Insurance Net of Government	Non-Medicare Class ("A")	Excluded Medicare Class ("B")							
<b>AstraZeneca</b>											
Zoledex	0.4%	18.7%	18.7%	4.2%	74.2%	19.3%	4.3%	76.4%	0.5%	0.1%	1.9%
<b>Bristol-Myers Squibb</b>											
Blenoxane	0.4%	78.3%	78.3%	12.7%	0.0%	86.1%	13.9%	0.0%	4.4%	0.7%	0.0%
Cytoxan	0.4%	53.9%	56.0%	5.1%	30.5%	61.1%	5.6%	33.3%	2.4%	0.2%	1.3%
Etopophos	0.4%	44.1%	44.1%	7.2%	43.0%	46.8%	7.6%	45.6%	2.7%	0.4%	2.6%
Paraplatin	0.4%	39.9%	39.9%	12.2%	34.4%	46.1%	14.1%	39.7%	3.3%	1.0%	2.9%
Rubex	0.4%	69.3%	69.3%	4.2%	26.4%	69.3%	4.2%	26.4%	0.0%	0.0%	0.0%
Taxol	0.4%	51.8%	51.8%	8.0%	29.5%	57.9%	9.0%	33.1%	5.7%	0.9%	3.2%
Vepesid	0.4%	44.1%	44.1%	7.2%	43.0%	46.8%	7.6%	45.6%	2.7%	0.4%	2.6%
<b>Johnson &amp; Johnson</b>											
Procit	0.4%	37.2%	37.2%	8.7%	48.8%	39.3%	9.2%	51.5%	1.7%	0.4%	2.3%
Remicade	0.4%	57.6%	57.6%	12.5%	23.4%	61.6%	13.4%	25.0%	3.3%	0.7%	1.3%
<b>Schering-Plough</b>											
albuterol											
Intron A	0.4%	58.4%	58.4%	15.2%	20.4%	62.2%	16.1%	21.7%	3.4%	0.9%	1.2%
perphenazine	0.4%	21.9%	21.9%	7.7%	42.5%	30.4%	10.7%	58.9%	6.8%	2.4%	13.1%
Proventil											
Temodar	0.4%	61.4%	61.4%	18.2%	16.9%	63.6%	18.9%	17.5%	1.5%	0.4%	0.4%

**Attachment J.5.a: NAMCS Data and Other Adjustments**

Drug Name	Allocating "Other" Across Two Classes				Totals Based on NAMCS Data				Totals Including Approximations				
	Class "A" Portion	Class "B" Portion	Other % to Class "A"	Other % to Class "B"	Total Non-Medicare Class ("A")	Total Medicare Exclude Class ("B")	Total Medicare Class ("C")	Medicare	Non-Medicare	Medicaid and Exclude	30	31	32
<b>AstraZeneca</b>													
Zoledex	81.7%	18.3%	0.3%	0.1%	19.5%	4.4%	76.2%	76.2%	19.5%	4.4%			
<b>Bristol-Myers Squibb</b>													
Blenoxane	86.1%	13.9%	3.3%	0.5%	86.1%	13.9%	0.0%	0.0%	86.1%	13.9%			
Cytoxan	91.6%	8.4%	4.2%	0.4%	62.5%	5.7%	31.8%	31.8%	62.5%	5.7%			
Etopophos	86.0%	14.0%	0.0%	0.0%	46.8%	7.6%	45.6%	45.6%	46.8%	7.6%			
Paraplatin	76.6%	23.4%	4.8%	1.5%	48.0%	14.7%	37.3%	37.3%	48.0%	14.7%			
Rubex	94.3%	5.7%	0.0%	0.0%	69.3%	4.2%	26.4%	26.4%	69.3%	4.2%			
Taxol	86.6%	13.4%	0.8%	0.1%	58.2%	9.0%	32.8%	32.8%	58.2%	9.0%			
Vepesid	86.0%	14.0%	0.0%	0.0%	46.8%	7.6%	45.6%	45.6%	46.8%	7.6%			
<b>Johnson &amp; Johnson</b>													
Procit	81.0%	19.0%	0.7%	0.2%	39.7%	9.3%	51.0%	51.0%	39.7%	9.3%			
Remicade	82.1%	17.9%	1.0%	0.2%	61.8%	13.5%	24.7%	24.7%	61.8%	13.5%			
<b>Schering-Plough</b>													
albuterol													
Intron A	79.4%	20.6%	0.5%	0.1%	62.3%	16.2%	21.6%	21.6%	19.4%	19.4%			
perphenazine	73.9%	26.1%	4.1%	1.4%	32.8%	11.6%	55.6%	55.6%	32.8%	32.8%			
Proventil													
Temodar	77.1%	22.9%	0.9%	0.3%	63.8%	18.9%	17.3%	17.3%	19.7%	19.7%			
									63.8%	63.8%			

## Notes to Attachment J.5.a

Column	Calculation
1	NAMCS or IMS NDTI data.
2	NAMCS or IMS NDTI data.
3	NAMCS or IMS NDTI data.
4	NAMCS or IMS NDTI data.
5	NAMCS or IMS NDTI data.
6	NAMCS or IMS NDTI data.
7	NAMCS or IMS NDTI data.
8	NAMCS or IMS NDTI data.
9	NAMCS or IMS NDTI data.
10	NAMCS or IMS NDTI data.
11	= sum Columns 1 through 10.
12	From Attachment J.7.b.
13	= (Column 2) * (1 - 5.2%, from Attachment J.7.b) - Column 12.
14	= (Column 5) + (Column 6) + (Column 13).
15	= (Column 2) * (5.2%, from Attachment J.7.b) + Column 4 + Column 7 + Column 10 + Column 12.
16	= Column 3.
17	= Column 14 / (Column 14 + Column 15 + Column 16).
18	= Column 15 / (Column 14 + Column 15 + Column 16).
19	= Column 16 / (Column 14 + Column 15 + Column 16).
20	= (Column 1 + Column 9) * Column 17.
21	= (Column 1 + Column 9) * Column 18.
22	= (Column 1 + Column 9) * Column 19.
23	= Column 14 / (Column 14 + Column 15).
24	= Column 15 / (Column 14 + Column 15).
25	= Column 8 * Column 23.
26	= Column 8 * Column 24.
27	= Column 14 + Column 20 + Column 25.
28	= Column 15 + Column 21 + Column 26.
29	= Column 16 + Column 22.
30	= Column 29, including approximations where NAMCS data are not available.
31	= Column 27, including approximations where NAMCS data are not available.
32	= Column 28, including approximations where NAMCS data are not available.

## Attachment J.5.b: Indirect Government Adjustments

<b>Federal Employees</b>	<u>Notes</u>
Number of Covered Beneficiaries in the FEHBP	9,000,000
Percent of Self-Insured FEHBP Employees	70%
Total Self-Insured FEHBP Beneficiaries	6,300,000

### **State Employees, Retirees and Other Local Employees Covered by State Employee Health Benefit Plans**

<u>Employees</u>	<u>Notes</u>
Total Number of Employees	3,901,252
Percent of Active Employees in HMO/POS Plans	46%
Percent of Self-Insured Employees	54%
Number of Self-Insured Employees	2,106,676
<u>Retirees</u>	<u>Notes</u>
Total Number of Retirees	1,333,385
Percent of Retirees in HMO/POS Plans	46%
Percent of Self-Insured Retirees	54%
Number of Self-Insured Retirees	720,028
Total Number of Self-Insured Employees and Retirees	2,826,704

### **Department of Defense Indirect Purchases**

Number of Prescriptions, TRICARE/CHAMPUS	12,513,448	13
Total Dispensed Prescriptions	3,100,000,000	14
Share of All Retail Rxs That Are Actually DoD	0.4%	15

### **Indirect Purchases on Behalf of Federal, State, and Local Government Employees**

Total Federal, State, and Local Self-Insured Beneficiaries	9,126,704	16
Privately Insured Beneficiaries: Employer Insurance	162,950,380	17
Privately Insured Beneficiaries: Individual Insurance	13,246,180	18
Total Privately Insured Beneficiaries	176,196,560	19
Total Government Self-Insured Employee Percentage	5.2%	20

## Notes to Attachment J.5.b

Row	Description
1	Source: Henry J. Kaiser Family Foundation, "Medicare Restructuring: The FEHBP Model", February 1999 (FEHBP Model), p. 4.
2	Source: FEHBP Model, p. 11. Sum total "Blue Cross/Blue Shield" percent and "Employee organization" percent.
3	= Row 1 * Row 2.
4	Source: The Segal Company, "1999 Survey of State Employee Health Benefit Plans" (Segal Report), Table 10, p. 23. Equals national "Total Employees Covered."
5	Source: Segal Report, Table 1, p. 3. Equals national "Active Employees in HMO/POS Plans, Percent".
6	= 100% - Row 5. This assumes that the remaining employees are self-insured.
7	= Row 4 * Row 6.
8	Source: Segal Report, Table 11, p. 25. Equals national "Total Retirees Covered."
9	= Row 5.
10	= Row 6.
11	= Row 8 * Row 10.
12	= Row 7 + Row 11.
13	TRICARE/CHAMPUS 2002 Chartbook of Statistics, Section VII, page 19 (FY 2001). ( <a href="http://199.211.83.250/Reports/Chartbook/2002/section7.cfm">http://199.211.83.250/Reports/Chartbook/2002/section7.cfm</a> accessed August 2003).
14	Drug Topics, March 18, 2002, "Still growing: steady, not stellar, growth marked the pharmaceutical market last year".
15	= Row 13 / Row 14.
16	= Row 3 + Row 12.
17	Source: Kaiser Family Foundation web site: <a href="http://statehealthfacts.kff.org">http://statehealthfacts.kff.org</a> . Click on "Health Coverage and Uninsured" and then "Distributed by Insurance Status". Accessed August 2003.
18	Source: Kaiser Family Foundation web site: <a href="http://statehealthfacts.kff.org">http://statehealthfacts.kff.org</a> . Click on "Health Coverage and Uninsured" and then "Distributed by Insurance Status". Accessed August 2003.
19	= Row 17 + Row 18.
20	= Row 16 / Row 19.

### **Attachment J.6: Damage Calculation Notes and Extrapolations**

AstraZeneca Class 2

Zoladex 2003-2004: Trend taken from 1998-2002

AstraZeneca Class 3

Zoladex 2003-2006: Trend from 1998-2002; 2006 equals (10/12)\*damages

Bristol-Myers Squibb Class 2

Cytoxan 1991-1992: Trend 1993-1997  
2003-2004: Average 2000-2002

Etopophos 2003-2004: Trend 1999-2002

Paraplatin 1991-1992: Trend 1993-2002  
2003-2004: Trend 1993-2002

Rubex 1991-1993: Trend 1994-1997  
2003-2004: Average 2000-2002

Taxol 2003-2004: Trend 2000-2002

Vepesid 1991-1992: (2/3)\*1993  
Given our understanding that there was no spread competition in 1991-1992, we estimate damages based on a conservative estimate of spreads.

2003-2004: Trend 2000-2002

Bristol-Myers Squibb Class 3

Paraplatin 2003-2004: Equal to 2002  
Based on increased spreads in 2002 and the trend in quantity, we estimate damages to be similar to 2002.

Johnson & Johnson Class 2

Procrit 2004: Equal to 2003  
Remicade 2004: Trend 2000-2003

Schering-Plough Class 2

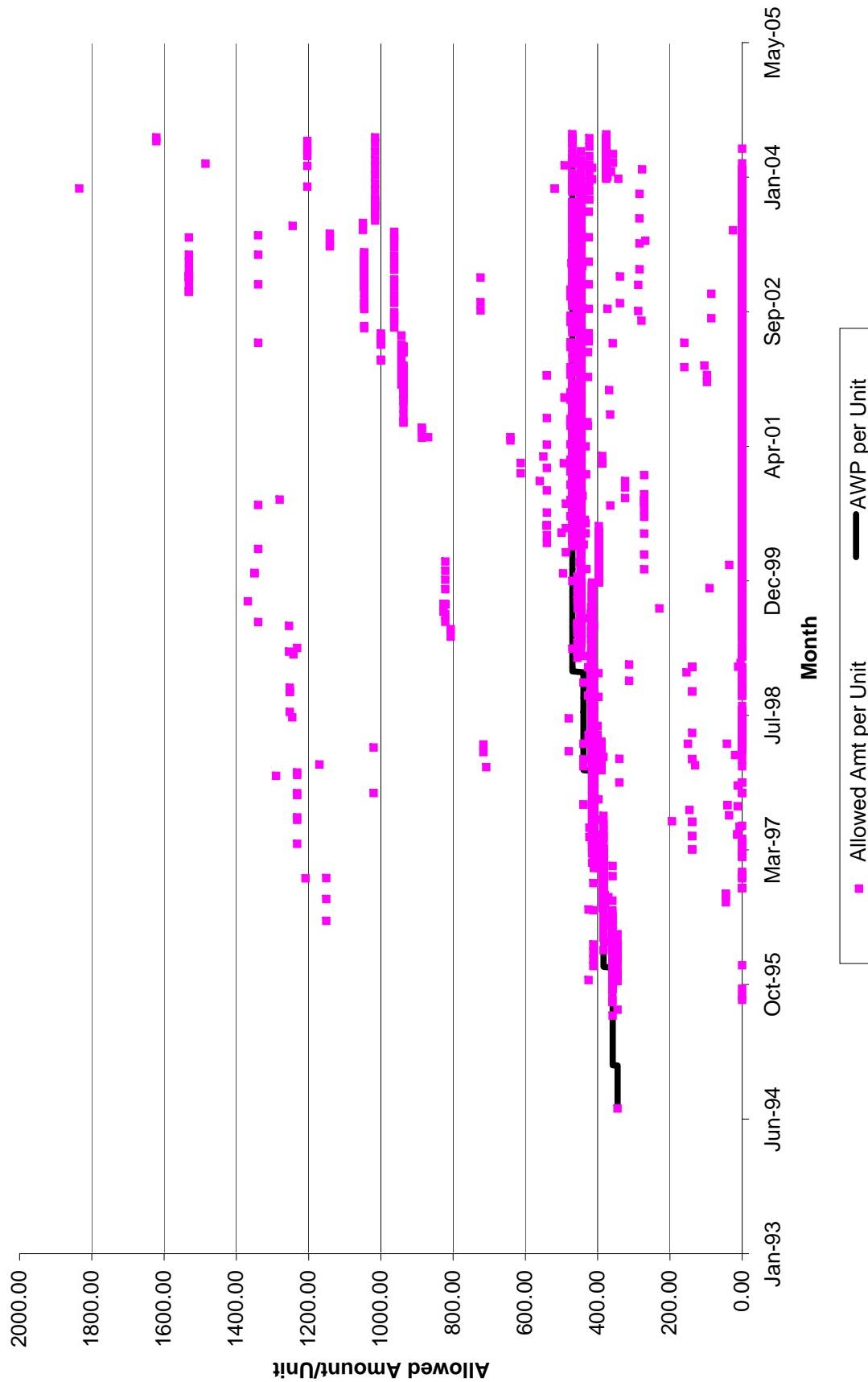
Albuterol 2004: Trend 2000-2003  
Intron 2004: Trend 2000-2003  
Perphenazine Damages set equal to zero  
Proventil 2004: Set equal to zero  
Temodar 2004: Trend 2000-2003

Schering-Plough Class 3

Intron 2004: 2004Q1\*4  
2005: Average 2002-2004  
2006: 10/12\*Average 2002-2004

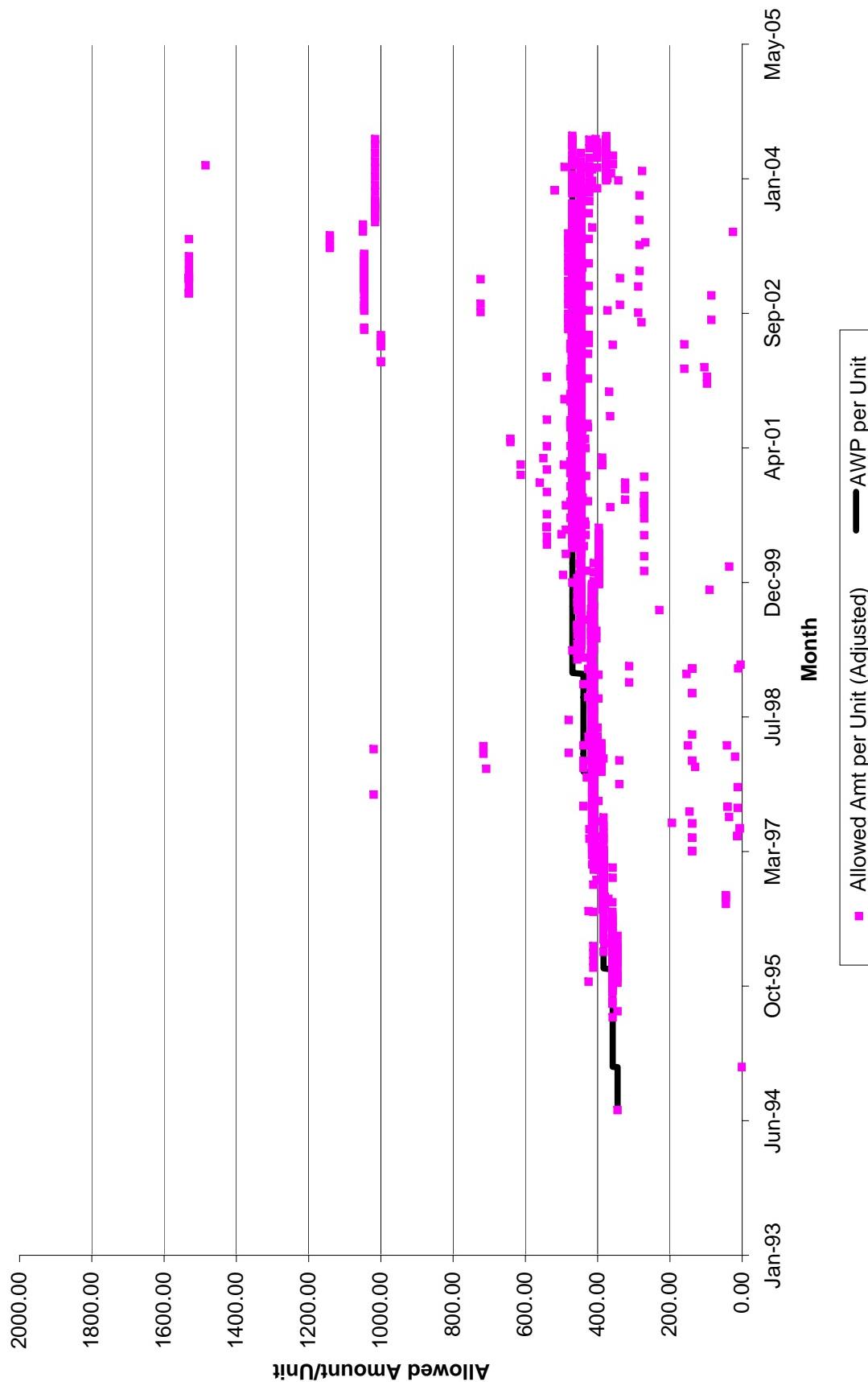
**Attachment K: Analysis of Zoladex Claims Data**

**Attachment K.1: Blue Cross Blue Shield of Kansas City Zoladex Reimbursement (J9202)**  
**NDC 00310-0960-36**



Direct Testimony of Raymond S. Hartman

**Attachment K.2: Blue Cross Blue Shield of Kansas City Zoladex Reimbursement (J9202)**  
**NDC 00310-0960-36**



Direct Testimony of Raymond S. Hartman

**Attachment L: Sample of Discovery Materials  
Demonstrating the Use of AWP as a Benchmark**

Deposition of Paula Pfankuch, September 14, 2004, pp. 25-26

## Transcript for Pfankuch, Paula 9/14/2004

Page 1	Page 2
<p>1 IN THE UNITED STATES DISTRICT COURT      2 FOR THE DISTRICT OF MASSACHUSETTS      3 - - -      4 In Re: PHARMACEUTICAL : MDL DOCKET NO.      5 INDUSTRY AVERAGE WHOLESALE : CIVIL ACTION #      6 PRICE LITIGATION : 01CV12257-PBS      7 -----      8 THIS DOCUMENT RELATES TO:      9 ALL ACTIONS      10 -----      11 The deposition of PAULA PFANKUCH,      12 called by the Defendants Pfizer, Pharmacia, and      13 Upjohn for examination, taken pursuant to the      14 Federal Rules of Civil Procedure of the United      15 States District Courts pertaining to the taking      16 of depositions, taken before KIMBERLY WINKLER      17 CHRISTOPHER, a Notary Public within and for the      18 County of Kane, State of Illinois, and a      19 Certified Shorthand Reporter of said State, taken      20 at 300 East Randolph Drive, Suite 2800, Chicago,      21 Illinois, on the 14th day of September, 2004, at      22 the hour of 9:40 o'clock a.m.</p>	<p>1 PRESENT:      2      3 THE WEXLER FIRM, LLP      4 BY: MS. ELIZABETH ANNE FEGAN      5 One North LaSalle Street      6 Suite 2000      7 Chicago, Illinois 60602      8 Appeared on behalf of the      9 Plaintiffs;      10      11 SHOOK HARDY &amp; BACON, L.L.P.      12 BY: MS. TIFFANY W. KILLOREN      13 2555 Grand Boulevard      14 Kansas City, Missouri 64108-2613      15 Appeared on Behalf of Aventis;      16 HOGAN &amp; HARTSON, LLP      17 BY: MS. SANDHYA P. KAWATRA      18 875 Third Avenue      19 New York, New York 10022      20 Appeared on behalf of      21 Bristol-Myers Squibb Co.;      22</p>
Page 3	Page 4
<p>1 MORGAN, LEWIS &amp; BOCKIUS, LLP      2 BY: MR. GREGORY F. WELLS      3 1111 Pennsylvania Avenue, NW      4 Washington, DC 20004      5 Appeared on behalf of Pfizer,      6 Pharmacia, and Upjohn;      7      8 BLUECROSS BLUESHIELD OF ILLINOIS      9 BY: MR. CHRISTOPHER T. ZAKRZEWSKI      10 300 East Randolph Street      11 Chicago, Illinois 60601-5099      12 Appeared on behalf of BlueCross      13 BlueShield of Illinois.      14      15      16      17      18      19      20      21      22</p>	<p>1 I N D E X      2 WITNESS PAGE      3 PAULA PFANKUCH      4 Direct Examination by Mr. Wells 5      5 Cross-Examination by Ms. Fegan 85      6 E X H I B I T S      7 PAGE      8 PFANKUCH NUMBER REFERRED TO      9      10 Exhibit Pfankuch 001 20      11      12 Exhibit Pfankuch 002 27      13      14 Exhibit Pfankuch 003 34      15      16 Exhibit Pfankuch 004 46      17      18 Exhibit Pfankuch 005 61      19      20 Exhibit Pfankuch 006 63      21      22 Exhibit Pfankuch 007 65</p>

## Transcript for Pfankuch, Paula 9/14/2004

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1 of Medicare.  
 2 Q. Okay.  
 3 A. So it's professional service as well as  
 4 things like DME or J codes where they are  
 5 administered in the physician office setting.  
 6 Q. Okay. So then for drugs administered  
 7 in a physician setting, they were subject to the  
 8 fee schedule?  
 9 A. Yes, they are.  
 10 Q. That's the underlying Medicare base fee  
 11 schedule?  
 12 A. Yes.  
 13 Q. Okay. And then how was that fee  
 14 schedule derived?  
 15 A. That fee schedule is based currently on  
 16 the dollars that Medicare publishes for those J  
 17 codes, and we use a percentage of the Medicare  
 18 allowable.  
 19 Q. And how long has that been the  
 20 methodology which you've used?  
 21 A. I believe that's been in place since  
 22 1999.

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1 Q. And how did you reimburse for drugs  
 2 administered by a physician before 1999?  
 3 A. Prior to 1999 the full service units --  
 4 those are our claim payment areas -- utilized the  
 5 AWP as published in the Red Book. I would like  
 6 to clarify for that last statement that it was a  
 7 percentage of the AWP published in the Red Book.  
 8 Q. Okay. And can you tell me what  
 9 BlueCross BlueShield of Illinois understood AWP,  
 10 or average wholesale price, to be?  
 11 A. Simply the average wholesale price.  
 12 Q. And the average wholesale price, what  
 13 do you mean by that?  
 14 A. Our understanding of it is very  
 15 limited, at least within the professional  
 16 reimbursement area. It is simply a term that we  
 17 would look to for pricing. There is not a  
 18 tremendous amount of knowledge about AWP  
 19 specifically other than it seems to be the  
 20 industry standard for the baseline reimbursement  
 21 for physician-administered drugs.  
 22 Q. When you say it's an industry standard,

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1 does that mean it's like a list price?  
 2 MS. FEGAN: Objection to form.  
 3 THE WITNESS: I don't know.  
 4 BY MR. WELLS:  
 5 Q. Have you ever heard the term "WAC" for  
 6 wholesale acquisition cost?  
 7 A. No, I haven't.  
 8 Q. What about the term "MAC" or "maximum  
 9 allowable cost"?

10 A. No, I haven't.  
 11 Q. Okay. I want to talk a little bit more  
 12 about the reimbursement methodologies.  
 13 MR. WELLS: Mark that as Exhibit 2,  
 14 please.  
 15 (Exhibit Pfankuch 002  
 16 marked as requested.)

17 BY MR. WELLS:  
 18 Q. If you could take a look through this  
 19 document, as you'll recall I think you and I and  
 20 Mr. Zakrzewski actually had a telephone  
 21 conversation trying to get some information about  
 22 this document. And I just wanted to either

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1 follow up on that conversation and also to, you  
 2 know, just ask some of the same questions we've  
 3 already talked about to get the information on  
 4 the record. So if you'll bear with me.  
 5 The third column of the document is  
 6 marked "1996 Med B Par Rates."  
 7 Can you explain what that means?  
 8 A. I'll start by saying this is a document  
 9 produced prior to my being in the department.  
 10 Q. Okay.  
 11 A. So I would like that to be included in  
 12 the record just so that you're aware of that.  
 13 My understanding is that the Med B par  
 14 rates are -- these are the rates published by  
 15 Medicare for their participating providers as of  
 16 1996.  
 17 Q. And the next column is marked as  
 18 "Recommended Rate."  
 19 What is that column?  
 20 A. Again, having not been here when this  
 21 document was produced, it appears that this would  
 22 have been the amount the team at that time in

Deposition of David Thomas, September 24, 2004, pp. 103-105

## Transcript for Thomas, David W. 9/24/2004

## Transcript for Thomas, David W. 9/24/2004

<p>Page 101</p> <p>1       medically appropriate.</p> <p>2           Let me give you a concrete example so</p> <p>3       that that answer is not misconstrued.</p> <p>4           If a specialist physician could</p> <p>5       render the -- could administer the</p> <p>6       pharmaceutical and be paid on a fee-for-service</p> <p>7       basis and the primary care physician could</p> <p>8       administer the pharmaceutical and the primary</p> <p>9       care physician is being compensated on a</p> <p>10      capitation basis where the primary care</p> <p>11      physician receives that same amount regardless</p> <p>12      of the number of incidents of service seen, the</p> <p>13      utilization management system will be designed</p> <p>14      to have that service rendered at the PCP's</p> <p>15      office rather than at the specialist's office.</p> <p>16   Q.     To accomplish that, does the capitation fee</p> <p>17      that is paid to primary care physicians have to</p> <p>18      build in an amount to cover what the primary</p> <p>19      care physician is expected to pay for</p> <p>20      physician-administered drugs?</p> <p>21   A.     It depends. If the physician-administered drug</p> <p>22      is being provided by the specialty pharmacy,</p>	<p>Page 102</p> <p>1       then the capitation payment should not include</p> <p>2       that, because the PCP is not incurring any cost</p> <p>3       in that particular setting.</p> <p>4           We're paying for it outside of that</p> <p>5       capitation service.</p> <p>6           - - -</p> <p>7       (There was a recess in the proceedings for lunch.)</p> <p>8           - - -</p> <p>9       MR. WELLS: I said before the break</p> <p>10      I was going to switch topics. Over the lunch</p> <p>11      break, I discovered one contract I believe I</p> <p>12      may have misfiled as a pharmacy side contract</p> <p>13      which looks like a specialty pharmacy contract.</p> <p>14       MR. KLEIN: Can you speak up?</p> <p>15       MR. WELLS: Yes. I discovered over</p> <p>16      the lunch break one contract I filed as a</p> <p>17      pharmacy contract which I believe now may be a</p> <p>18      specialty pharmacy contract. I want to</p> <p>19      backtrack and ask a few questions about that,</p> <p>20      and then we'll move on to pharmacy side stuff.</p> <p>21       If we can mark this as Exhibit 5,</p> <p>22      please.</p>
<p>Page 103</p> <p>1           - - -</p> <p>2       (Exhibit Thomas 005 marked for</p> <p>3       identification.)</p> <p>4           - - -</p> <p>5 BY MR. WELLS:</p> <p>6 Q.     Exhibit 5 is a document marked Ancillary</p> <p>7       Services Agreement between Three Rivers Health</p> <p>8       Plans, Inc., and the line is blank, but we can</p> <p>9       see from the bottom of the page it's with a</p> <p>10      company called ASD Direct, Stadtlander's</p> <p>11      Pharmacy. It has the Bates numbers</p> <p>12      TRH AWP 000027 through 49.</p> <p>13       Is this, in fact, a specialty</p> <p>14      pharmacy contract?</p> <p>15 A.     That would be my understanding, yes.</p> <p>16 Q.     What products are covered by this contract?</p> <p>17 A.     You'd have to refer to Attachment A to the</p> <p>18       agreement, which is TRH AWP 000041 through</p> <p>19      000043.</p> <p>20 Q.     What does that attachment tell you are the</p> <p>21      products covered by this agreement?</p> <p>22 A.     There are antihemophiliac factor products --</p>	<p>Page 104</p> <p>1       There's compensation for</p> <p>2       antihemophiliac factor products; and there's a</p> <p>3       listing of J codes for factor Roman numeral</p> <p>4       VIII products and for factor Roman numeral IX</p> <p>5       products; there are J code listings for</p> <p>6       anti-inhibitor products; J code listings for</p> <p>7       factor Roman numeral VII products; there are</p> <p>8       J codes listed for Von Willebrand,</p> <p>9       W-I-L-L-E-B-R-A-N-D, disease products; there</p> <p>10      are J codes listed for hemophilia-related</p> <p>11      products; and there are some miscellaneous</p> <p>12      provisions.</p> <p>13 Q.     How is the specialty pharmacy compensated for</p> <p>14      the drug products under this contract?</p> <p>15 A.     If you look at Attachment A on the pages in the</p> <p>16      sections that have the J code listings that</p> <p>17      describe the products, the far right column</p> <p>18      will specify reimbursement for each of those</p> <p>19      products, and the reimbursement for all of them</p> <p>20      is specified as a percentage of AWP.</p> <p>21 Q.     When you say everything or all of them are</p> <p>22      specified as a percentage of AWP, is it</p>

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1 accurate then that all of these drugs are  
 2 compensated at some discount off of AWP?  
 3 A. Yes. This is mathematically the reverse of the  
 4 statement you see in the other contracts where  
 5 it was -- instead of saying AWP less a  
 6 percentage, this says a percentage of AWP.  
 7 It's a varying mathematical manner of  
 8 expressing the same concept.  
 9 Q. Do you know how the reimbursement rates in this  
 10 attachment were arrived at?  
 11 A. Negotiated between the payer and the provider.  
 12 Q. What was Three Rivers trying to accomplish in  
 13 those negotiations?  
 14 A. We were trying to purchase the products covered  
 15 by this contract from a responsible bidder at  
 16 the lowest price possible.  
 17 Q. Do you feel you were successful in that  
 18 pursuit?  
 19 MR. KRASIK: Objection.  
 20 THE WITNESS: I'm not sure I have the  
 21 ability to comment upon whether or not this is  
 22 cost-effective in the industry.

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1 BY MR. WELLS:  
 2 Q. Has anyone at Three Rivers ever expressed  
 3 dissatisfaction with the reimbursement that  
 4 Three Rivers was paying to the ASD Direct  
 5 Stadtlander's Pharmacy for these products?  
 6 A. No.  
 7 Q. Is it fair to say that the amount of the  
 8 discount off of AWP or the way it's expressed  
 9 here, the percentage payment of AWP varies from  
 10 drug to drug?  
 11 A. Yes.  
 12 Q. What is the range of that variance?  
 13 A. Based upon my review of the document, the  
 14 lowest payment mechanism appears to be 75  
 15 percent of AWP, and I believe the highest  
 16 payment formula is specified as 90 percent of  
 17 AWP.  
 18 Q. And expressed the other way, that would be from  
 19 AWP minus 10 percent to AWP minus 25 percent.  
 20 Is that correct?  
 21 A. That's the way the math would work.  
 22 Q. Now, as promised, I would like to move on to

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1 another subject, specifically the subject of  
 2 drugs dispensed through pharmacies.  
 3 How does Three Rivers reimburse for  
 4 drugs dispensed through pharmacies?  
 5 A. We pay the lesser of, for brand name, AWP minus  
 6 15 or the usual and customary charge.  
 7 For generics, we pay the lesser of  
 8 plan MAC or usual and customary, and there is a  
 9 \$2 dispensing fee.  
 10 MR. KLEIN: Can you repeat that  
 11 again?  
 12 THE WITNESS: For brand name, the  
 13 reimbursement model is the lesser of AWP minus  
 14 15 or usual and customary.  
 15 For generic, the reimbursement model  
 16 is plan MAC list price or usual and customary,  
 17 and there is a \$2 dispensing fee.  
 18 BY MR. WELLS:  
 19 Q. How long has Three Rivers reimbursed on that  
 20 basis?  
 21 A. Since at least early 2003. I believe late  
 22 2002, early 2003 was the last time we changed

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1 our reimbursement rates for providers.  
 2 Q. Who is Three Rivers Health making this  
 3 reimbursement to?  
 4 A. Those monies ultimately go into --  
 5 They flow through AdvancePCS, our  
 6 PBM, to the provider, the pharmacy.  
 7 Q. So Three Rivers used AdvancePCS then as a PBM?  
 8 A. Yes.  
 9 Q. How long have you been used AdvancePCS as your  
 10 PBM?  
 11 A. '97 or '98.  
 12 Q. How was Three Rivers reimbursing for  
 13 pharmaceuticals before it started doing  
 14 business with AdvancePCS?  
 15 MR. KLEIN: Can everybody speak up?  
 16 BY MR. WELLS:  
 17 Q. Sorry. How was Three Rivers reimbursing for  
 18 pharmaceuticals prior to when it began doing  
 19 business with AdvancePCS?  
 20 A. We have always reimbursed on --  
 21 My understanding is we have always  
 22 reimbursed on an AWP minus discount for brand

FCC 000495

**Schedule 1  
Of the  
Network K Attachment  
of the  
BlueCross BlueShield of Tennessee  
Physician Agreement for a Physician Specialist**

**Schedule 1-B (Clinical Lab Maximum Allowable Fee Schedule)**

Reimbursement for clinical laboratory services will be 85% of the published Medicare Part B Clinical Laboratory Fee Schedule for Tennessee.

Annual updates to the Maximum Allowable Fee Schedule for existing codes will be effective with date of service April 1.

For codes without a published Medicare clinical laboratory fee, reimbursement is based on a reasonable allowable as determined by BlueCross BlueShield of Tennessee.

Annual updates may result in increases and decreases in fees.

**Schedule 1-C (Immune Globulin, Vaccine, and Toxoid Maximum Allowable Fee Schedule)**

The Maximum Allowable Fee Schedule is based on Average Wholesale Price (AWP) as defined by the BlueCross BlueShield of Tennessee Reimbursement Policy for Immune Globulins, Vaccines and Toxoids.

Updates to the Maximum Allowable Fee Schedule for existing codes will be made in accordance with the BlueCross BlueShield of Tennessee Reimbursement Policy for Immune Globulins, Vaccines and Toxoids.

Due to the frequent changes in AWP, BlueCross BlueShield of Tennessee reserves the right to update the Maximum Allowable Fee Schedule without prior notification.

Updates to the Maximum Allowable Fee Schedule may result in increases and decreases in fees.

**Schedule 1-D (Injectable Drug Maximum Allowable Fee Schedule)**

The Maximum Allowable Fee Schedule is based on Average Wholesale Price (AWP) as defined by the BlueCross BlueShield of Tennessee Reimbursement Policy for Infusion Therapy, Immunosuppressive, Nebulizer, Chemotherapy and Other Injectable Drugs.

Updates to the Maximum Allowable Fee Schedule for existing codes will be made in accordance with the BlueCross BlueShield of Tennessee Reimbursement Policy for Infusion Therapy, Immunosuppressive, Nebulizer, Chemotherapy and Other Injectable Drugs.

Due to the frequent changes in AWP, BlueCross BlueShield of Tennessee reserves the right to update the Maximum Allowable Fee Schedule without prior notification.

Updates to the Maximum Allowable Fee Schedule may result in increases and decreases in fees.

08/30/2001

TCC 000474

COPY

**EXHIBIT B**  
**Southwest Physician Association**

The UNICARE fee schedule is based on the multiplier(s) listed below and the 2002 Medicare participating fee schedule for Locality 11 - Dallas, Texas, except as noted below. Inclusion of a value on the Medicare schedule does not imply UNICARE coverage or payment. Where Medicare's new procedure codes will be based on the applicable Medicare resource based relative value units.

UNICARE will allow the lesser of 80% of covered billed charges or the maximum allowable under UNICARE's pricing policies.

**CPT codes**

<b>Surgery</b>	10000 - 69999	150%
<b>Radiology</b>	70000 - 79999	150%
<b>Pathology</b>	88000 - 89999	150%
<b>Medicine</b>	99201 - 99380, 99431 - 99999 99381 - 99429 90801 - 90911 All Other Medicine Codes	120% 120% 120% 120%

**Except as Follows**

<b>Clinical Lab</b>	80000-87999	Unicare Lab Fee Schedule*
Vaccines/Immune Globulins/and other drugs *See Pharmacy description below		100% of Unicare-based AWP
<b>Anesthesia</b>	00100-01999	\$48 CF
(Based on ASA unit values and 15 minute time units)		
<b>Administration of Vaccines</b>	90471 90472 90473 90474	\$4.19 \$4.19 \$3.00 \$3.00

\*Codes 80002-87999 with modifier -26 (Excluding codes 83020, 83912, 84165, 84181, 84182, 85390, 85576, 86255, 86256, 86320, 86325, 86327, 86334, 87164, 87207) are not reimbursed by UNICARE.

**Pharmacy (including infusion therapy drugs):** maximum allowable reimbursement based on average wholesale price (AWP) according to UNICARE selected published market data, including, but not limited to, sources such as the Drug Topics Red Book. Oral prescription drugs dispensed in the physician's office will be denied as not payable, and the Member may not be billed by physician.

**Durable Medical Equipment, Supplies (including, but limited to, infusion therapy supplies), Prosthetics and Orthotics:** maximum allowable reimbursement will be determined by UNICARE using claims data and/or external data. Reimbursement rates will be based on whether the equipment is new, used or rented, as identified by the appropriate HCPCS Level II code modifier. Codes not identified by modifier will be considered as rentals. **All other HCPCS Level II Codes:** The maximum allowable reimbursement will be determined by UNICARE using claims data and/or external data.

**Default for 0 Value Code: 80% of Covered Billed Charge**

TCC 001000

## **Payment Appendix - All Payor Non-Medicare/Non-Medicaid**

Unless another Appendix to this Agreement applies specifically to certain Members, the provisions of this Appendix apply to Health Services rendered by Provider to Members covered by Benefit Contracts sponsored, issued or administered by all Payors.

### **SECTION 1 Definitions**

**Fee Maximum:** The maximum fees for Health Services rendered by Participating Providers, as determined from time to time by Plan. The Fee Maximums for the same Health Services rendered pursuant to different Benefit Contracts may vary. A sample of the most recent Fee Maximums are available to Provider and Corporation upon request.

### **SECTION 2 Payment**

**Payment for Health Services Rendered to Members.** Health Services rendered by Provider to Members, Payor shall pay Provider the lesser of (1) Provider's Customary Charge for such Health Services, less any applicable Member Expenses; or (2) the Fee Maximum for such Health Services, less any applicable Member Expenses.

For purposes of this Agreement, Fee Maximums will be as follows:

- 120% Dallas 2001 Medicare RBRVS for Choice, HMO, EPO and POS products. Surgical Pathology will be reimbursed at 130% of Dallas 2001 Medicare RBRVS.
- 130% of Dallas 2001 Medicare RBRVS for Options PPO products. Surgical Pathology will be reimbursed at 145% of Dallas 2001 Medicare RBRVS.
- Clinical laboratory services will be reimbursed at UnitedHealthcare's National Laboratory rates.
- HCPC codes will be reimbursed at 100% of Dallas 2001 Medicare RBRVS.
- Immunizations and drugs will be reimbursed at 100% of AWP; AWP amounts are updated twice a year.
- Anesthesia conversion factor will be \$47 per ASA Unit.
- All unlisted procedure codes would be reimbursed at 65% of customary charges. As relative values are established, allowables will represent reimbursements based on the year relative values are available.
- UnitedHealthcare annually reviews the current HCFA RVU rules and adopts a modified professional/technical split.
- Contracted rates would remain in place for a minimum of two years.

FCC 000613

**AMENDMENT TO CONSULTING PHYSICIAN SERVICES AGREEMENT**

This Amendment to Consulting Physician Services Agreement is made by and between **BETTER HEALTH PLANS, INC.**, with offices located at 300 Oxford Drive, Monroeville, PA 15146 (hereinafter referred to as "Health Plan") and G. Gary Tian (hereinafter referred to as "Consulting Physician").

**WHEREAS**, Health Plan and Consulting Physician have entered into a Consulting Physician Services Agreement (hereinafter referred to as "Agreement") concerning the provision of health care services to Members of Health Plan;

**WHEREAS**, Health Plan and Consulting Physician desire to make certain amendments to the Agreement pursuant to Article IV, Section A of Agreement;

**THEREFORE**, in consideration of the premises and mutual promises contained herein, for valuable consideration and intending to be legally bound hereby, Health Plan and Consulting Physician modify the Agreement as follows:

1. Attachment A is amended to the following:

Health Plan shall compensate Consulting Physician 80% of the applicable fee in the Better Health Fee Schedule in effect on the date Consulting Physician Services are rendered.

The Better Health Fee Schedule shall mean the Medicare Fee Schedule in effect as of July 1, 2000 for Covered Services subject to the following:

(a) New procedures added to the Medicare Fee Schedule shall be added to the Better Health Fee Schedule provided that the procedures are Covered Services under one or more of Health Plans' benefit plans. The effective date of a new procedure shall be the date the Health Plan adds the new procedure to the Better Health Fee Schedule, unless otherwise specified by Health Plan. The fee for a new procedure shall be the initial fee specified by Medicare, unless otherwise specified by Health Plan;

(b) Procedures deleted by Medicare from the Medicare Fee Schedule shall be likewise deleted in the Better Health Fee Schedule. Health Plan shall decide the effective date for said deletions;

(c) The Better Health Fee Schedule shall be implemented in accordance with Medicare policies and procedures, unless otherwise specified by Health Plan; and

(d) Such other modifications deemed appropriate by Health Plan upon notice to provider.

Health Plan shall compensate Consulting Physician at 90% of the Average Wholesale Price (AWP) for all drugs. These drugs shall be billed with the appropriate NDC codes. Please refer to the Provider Services Manual for prior authorization requirements.

Except as modified herein, all the terms and the conditions of the Agreement remain in full force and effect.

This Amendment is subject to the approval of the Bureau of TennCare and/or any other applicable governing State or federal regulatory agency. Health Plan may not sign this Amendment until Health Plan receives such approval.

AET 004285-86

REDACTED

Effective Date: 10/15/2002  
10/15/02

AMENDMENT

November 15, 2002

This Amendment is made as of October 15, 2002 (Effective Date), between Aetna Health of North Texas Inc., a Texas corporation, on behalf of itself and its Affiliates (hereinafter referred to as "Company") and (hereinafter referred to as "Provider").

REDACTED

WHEREAS, the parties have entered into a Facility Agreement ("Agreement") to provide health care services to Members;

WHEREAS, the parties wish to amend the Agreement to revise the Diagnostic Radiology and Imaging Services and Compensation Schedule and Service and Billing Location Form as provided herein;

NOW, THEREFORE, in consideration of the mutual promises and undertakings contained herein, the parties agree to be legally bound as follows:

1. The Diagnostic Radiology and Imaging Services and Compensation Schedule is deleted and replaced in its entirety by the attached Facility Services and Compensation Schedule annexed hereto;
2. The Service and Billing Location Form is deleted and replaced in its entirety by the attached Service and Billing Location Form annexed hereto;
3. All other terms and provisions of the Agreement not amended hereby shall remain in full force and effect. In the event of any inconsistency between the terms of this Amendment and the Agreement, the terms of this Amendment shall govern and control.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed below.

Accepted By:

PROVIDER

By:

REDACTED

(Signature)

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: 10/15/02

Tax I.D. Number: \_\_\_\_\_

COMPANY  
Aetna Health of North Texas Inc.,  
a Texas corporation

By: J. Blanford

(Signature)

Printed Name: J.T. Blanford

Title: Regional Network Operations Manager

Date: OCT 16 2002

CONFIDENTIAL PURSUANT  
TO PROTECTIVE ORDER

## Sample REDACTED Fee Schedule\*\*

CPT-4 & HCPCS	Procedure Description	HMO Reimbursement OFF	HMO Reimbursement NOF	Non-HMO Reimbursement OFF	Non-HMO Reimbursement NOF
J1441	FILGRASTIM (NEUPOGEN, G-CSF) 480 MCG				
J2430	PAMIDRONATE (AREDIA) 30 MG				
J2820	SARGRAMOSTIM (LEUKINE, GM-CSF) 50 MCG				
J9000	DOXORUBICIN (ADRIAMYCIN) 10MG PFS				
J9001	DOXORUBICIN HCL LIPOSOME (DOXIL) 10 MG				
J9045	CARBOPLATIN (PARAPLATIN) 50MG				
J9062	CISPLATIN (PLATINOL), 50 MG				
J9170	DOCETAXEL (TAXOTERE) 20 MG				
J9201	GEMCITABINE HCl (GEMZAR) 200 MG				
J9206	CAMPTOSAR (IRINOTECAN) 20 MG				
J9217	LEUPROLIDE ACETATE (LUPRON) FOR DEPOT SUSP. 7.5 MG	643.77		643.77	
J9265	PACLITAXEL (TAXOL) 30MG				
J9310	RITUXIMAB (RITUXAN) 100MG				
J9350	TOPOTECAN (HYCAMTIN) 4 MG				
J9355	TRASTUZUMAB (HERCEPTIN) 10 MG				
J9390	VINORELBINE TARTRATE (NAVELBINE) 10 MG				
Q0136	EPOETIN INJ PER 1000 UNITS				
Q0180	DOLASETRON MESYLATE (ANZEMET) 100 MG PO				
<b>Reimbursement for Services Performed at Facility</b>					
74160	Contrast CAT scan of abdomen				
77263	Therap Rad Tx Planning; Compix				
77280	Therap Rad Simulat-Aided Field; Sim				
77290	Therap Rad Simulat-Aid Fld; Compix				
77295	Tx Rad Sim-Aided Field Setting; 3-D				
77300	Basic Rad Dosimetry Calculat-By Md				
77315	Teletherapy Isodose Plan; Compix				
77331	Spec Dosimetry-Prescrib By Tx Phys				
77334	Tx Devic Design & Construct; Compix				
77336	Cont Med Physics Cons Per Wk Ther				
77413	Rad Tx Deliv-3/More Areas; 6-10 Mev				
77414	Rad Tx Deliv-3/More Areas; 11-19 Mev				
77416	Rad Tx Deliv-3/More Areas; 20 Mev				
77417	Therap Rad Port Film				
77427	Wk Rad Therap Mgmt				

CONFIDENTIAL PURSUANT  
TO PROTECTIVE ORDER

AETNA 003340

AET 004286

TCC 000356-361

~~CONFIDENTIAL AND PROPRIETARY~~

**HMO Blue® Texas**  
**Specialty Injectable Drug Program**

HCPCS Billing Code	Drug Name	Discount
J0476	LOIRESAL INTRATHECAL	AWP- 15%
J0205	CEREDASE	AWP- 1%
J0585	BOTOX	AWP- 15%
J0587	MYOBLOC	AWP- 15%
J0725	CHORIONIC GONADOTROPIN	AWP- 30%
J0740	VISTIDE	AWP- 15%
J0880	ARANESP	AWP- 15%
J1050, J1055	DEPO-PROVERA *	AWP - 15%
J1260	ANZEMET	AWP- 15%
J1438	ENBREL	AWP- 16%
J1440	NEUPOGEN	AWP- 15%
J1550	BAYGAM	AWP- 30%
J1561, J1563	GAMIMUNE N GAMMAGARD S/D GAMMAR-P IVEEGAM SANDOGLOBULIN PANGLOBULIN POLYGAM S/D* VENOGLOBULIN	AWP- 15%
J1565	RESPIGAM	AWP- 20%
J1620	FACTREL	AWP- 15%
J1626	KYTRIL	AWP- 15%
J1645	FRAGMIN	AWP- 15%
J1650	LOVENOX	AWP- 15%
J1655	INNOHEP	AWP- 15%
J1745	REMICADE	AWP
J1785	CEREZYME	AWP- 2%
J1825	AVONEX REBIF*	AWP- 16%
J1830	BETASERON	AWP- 15%
J1950	LUPRON	AWP- 15%
J2352, S0079	SANDOSTATIN	AWP- 15%
J2355	NEUMEGA	AWP- 20%
J2405, S0181	ZOFRAN	AWP- 18%
J2430	AREDIA	AWP- 15%
J2500	ZEMPLAR	AWP- 15%
J2790	RHOGAM* BAYRHO-D*	AWP - 16%
J2820	LEUKINE	AWP- 20%

AWP is the average wholesale price as published by MediSpan.

\*Drug available from McKesson Specialty Pharmaceuticals 1/6/03 however, discount pricing for reimbursement will not be effective until 3/15/03\*

The information contained herein is confidential. This is not a guaranty of payment for a service or that the reimbursement will be accurate on the date of service. Providing this schedule does not create a contractual obligation to reimburse at the indicated level. Reimbursement levels and codes are subject to change.



**BlueCross BlueShield  
of Texas**

*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company\**  
*Southwest Texas HMO, Inc. d/b/a HMO Blue® Texas*  
*\*Independent Licensees of the Blue Cross and Blue Shield Association*

**HMO Blue® Texas**  
**Specialty Injectable Drug Program**

J2940	PROTROPIN	AWP- 15%
J2941	GENOTROPIN GENOTROPIN MINIQUICK HUMATROPE NORDITROPIN NUTROPIN NUTROPIN AQ NUTROPIN DEPOT SAIZEN SEROSTIM	AWP- 15%
J3240	THYROGEN	AWP- 15%
J3490	CETROTIDE COPAXONE FERTINEX FOLLISTIM GONAL-F KINERET ORGARAN OVIDREL PEG-INTRON PERGONAL PEGASYS* REBETRON REPRONEX SYNAGIS VIADUR KIT ZOMETA	AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 18% AWP- 15% AWP- 16% AWP- 15% AWP- 20% AWP- 19% AWP- 15% AWP- 15%
J7190	ALPHANATE HEMOFIL-M KOATE-DVI* KOGENATE FS MONARC-M MONOCLOATE-P	AWP- 15%
J7192	HELIXATE* HELIXATE-FS* RECOMBINATE REFACTO*	AWP- 10%
J7193	ALPHANINE SD* MONONINE*	AWP-20%

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of Texas

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**HMO Blue® Texas**  
**Specialty Injectable Drug Program**

J7195	PROFILNINE SD* PROPLEX T* BENEFIX	AWP-25%
J7316	HYALGAN BIOLON PROVISC VITRAX	AWP- 15%
J7320	SYNVISC*	AWP-15%
J9202	ZOLADEX	AWP- 20%
J9212	INFERGEN	AWP- 15%
J9213	ROFERON-A	AWP- 15%
J9214	INTRON A	AWP- 15%
J9216	ACTIMMUNE	AWP- 15%
J9217	LUPRON	AWP- 15%
J9218	LEUPROLIDE LUPRON	AWP- 15%
Q0136, Q9920-Q9940	EPOGEN PROCRIT	AWP- 15%
Q2021	REFLUDAN	AWP- 15%

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*Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company\**  
*Southwest Texas HMO, Inc.\* db/a HMO Blue® Texas*  
*\*Independent Licensees of the Blue Cross and Blue Shield Association*

**CONFIDENTIAL AND PROPRIETARY****PROPERTY OF TEXAS CANCER CARE**HMO Blue® Texas  
Specialty Injectable Drug Program

J-Code	Drug Name	Discount
J0476	LORESAL INTRATHECAL	AWP- 15%
J0205	CEREDASE	AWP- 1%
J0585	BOTOX	AWP- 15%
J0587	MYOBLOC	AWP- 15%
J0725	CHORIONIC GONADOTROPIN	AWP- 30%
J0740	VISTIDE	AWP- 15%
J1050, J1055	DEPO-PROVERA *	AWP - 15%
J1260	ANZEMET	AWP- 15%
J1438	ENBREL	AWP- 16%
J1440	NEUPOGEN	AWP- 15%
J1550	BAYGAM	AWP- 30%
J1561, J1563	GAMIMUNE N GAMMAGARD S/D GAMMAR-P IVEEGAM SANDOGLOBULIN PANGLOBULIN POLYGAM S/D* VENOGLOBULIN	AWP- 15%
J1565	RESPIGAM	AWP- 20%
J1620	FACTREL	AWP- 15%
J1626	KYTRIL	AWP- 15%
J1645	FRAGMIN	AWP- 15%
J1650	LOVENOX	AWP- 15%
J1655	INNOHEP	AWP- 15%
J1745	REMICADE	AWP
J1785	CEREZYME	AWP- 2%
J1825	AVONEX REBIF*	AWP- 16%
J1830	BETASERON	AWP- 15%
J1950	LUPRON	AWP- 15%
J2352, S0079	SANDOSTATIN	AWP- 15%
J2355	NEUMEGA	AWP- 20%
J2405, S0181	ZOFRAN	AWP- 18%
J2430	AREDIA	AWP- 15%
J2500	ZEMPLAR	AWP- 15%
J2790	RHOGAM*	AWP - 16%
J2820	LEUKINE	AWP- 20%
J2940	PROTROPIN	AWP- 15%

AWP is the average wholesale price as published by MediSpan.

\*Drug available from McKesson Specialty Pharmaceuticals 1/6/03 however, discount pricing for reimbursement will not be effective until 3/15/03\*

The information contained herein is confidential. This is not a guaranty of payment for a service or that the reimbursement will be accurate on the date of service. Providing this schedule does not create a contractual obligation to reimburse at the indicated level. Reimbursement levels and codes are subject to change.



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**HMO Blue® Texas  
Specialty Injectable Drug Program**

J2941	GENOTROPIN GENOTROPIN MINIQUICK HUMATROPE NORDITROPIN NUTROPIN NUTROPIN AQ NUTROPIN DEPOT SAIZEN SEROSTIM	AWP- 15%
J3240	THYROGEN	AWP- 15%
J3490	ARANESP CETROTIDE COPAXONE FERTINEX FOLLISTIM GONAL-F KINERET ORGARAN OVIDREL PEG-INTRON PERGONAL PEGASYS* REBETRON REPRONEX SYNAGIS ZOMETA	AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 15% AWP- 18% AWP- 15% AWP- 16% AWP- 15% AWP- 20% AWP- 19% AWP- 15%
J7190	ALPHANATE HEMOFIL-M KOATE-DVI* KOGENATE FS MONARC-M MONOCLOATE-P	AWP- 15%
J7192	HELIXATE* HELIXATE-FS* RECOMBINATE REFACTO*	AWP- 10%
J7193	ALPHANINE SD* MONONINE*	AWP-20%

AWP is the average wholesale price as published by MediSpan.

\*Drug available from McKesson Specialty Pharmaceuticals 1/6/03 however, discount pricing for reimbursement will not be effective until 3/15/03\*

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**HMO Blue® Texas  
Specialty Injectable Drug Program**

J7195	PROFILNINE SD* PROPLEX T* BENEFIX	AWP-25%
J7316	HYALGAN BIOLON PROVISC VITRAX	AWP-15%
J7320	SYNVISC*	AWP-15%
J9202	ZOLADEX	AWP- 20%
J9212	INFERGEN	AWP- 15%
J9213	ROFERON-A	AWP- 15%
J9214	INTRON A	AWP- 15%
J9216	ACTIMMUNE	AWP- 15%
J9217	LUPRON	AWP- 15%
J9218	LEUPROLIDE LUPRON	AWP- 15%
Q0136, Q9920-Q9940	EPOGEN PROCIT	AWP- 15%
Q2021	REFLUDAN	AWP- 15%

AWP is the average wholesale price as published by MediSpan.

\*Drug available from McKesson Specialty Pharmaceuticals 1/6/03 however, discount pricing for reimbursement will not be effective until 3/15/03\*

The information contained herein is confidential. This is not a guaranty of payment for a service or that the reimbursement will be accurate on the date of service. Providing this schedule does not create a contractual obligation to reimburse at the indicated level. Reimbursement levels and codes are subject to change.



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FCC 000299



# BAPTIST & PHYSICIANS

August 2, 1999

Dear IDS Provider,

Effective September 1, 1999, Baptist & Physicians IDS will reimburse all drugs billed with HCPCS J codes at average wholesale price (AWP). This new reimbursement policy will be for all plans for which we pay claims (Cigna, Healthsource, Prudential, Baptist POS). The AWP fee schedule will be updated on a quarterly basis. We will monitor to see if there are any large, sudden increases in an individual drug cost. A withhold will not be applied for J code reimbursement.

To assist you in obtaining the most cost-effective drugs for all of your patients, you are encouraged to participate in our Physician Purchasing Network. This is offered through Baptist & Physicians and offers substantial discounts on the following:

- pharmaceuticals
- medical/surgical supplies
- capital equipment
- x-ray film
- office supplies and lab supplies

If you would like further information about the Physician Purchasing Network, please contact Marie Almond at (901)227-5505 or Will Batts at (901)227-5522.

If you have any questions about the new reimbursement policy for J codes, please contact Provider Relations at (901)752-5280.

Sincerely,

David Seal  
Executive Director  
Baptist & Physicians IDS

Robert Hartley, MD  
Medical Director  
Baptist Physicians Organization

TCC 000267

ADDENDUM A

TO PROVIDER SERVICES AGREEMENT

HMO AND POINT OF SERVICE BENEFIT PROGRAMS

A. STANDARD HMO BENEFIT PROGRAMS; POINT OF SERVICE BENEFIT PROGRAMS

1. Compensation.

- 1.1 Compensation to Physician and Group Provider for Physician Capitated Services. When Physician and Group Provider is compensated on a Capitation Compensation basis, Physician or Group Provider shall render Physician Capitated Services, as set forth on Exhibit 2 of this Addendum. As compensation for providing Physician Capitated Services, AmCare shall pay Physician the Capitation Compensation as set forth in Exhibit 1 of this Addendum for each Member eligible to receive such services from Physician during a particular month. Such payment shall be made by AmCare on or before the fifteenth (15th) day of such month. The payment of Capitation Compensation for any month shall not reflect Members added after the first (1st) but prior to the fifteenth (15th) day of the month. However, the capitation payment for the next full month after the month in which such Members were added shall reflect such Members retroactively for the month, as if they had been Members as of the first (1st) day of the month in which they were added. Members added after the fifteenth (15th) of the month shall be reflected in the capitation payment beginning with the next full month after the month in which they were added, but shall not be paid for retroactively for the month in which they were added. AmCare's payment shall be subject to the provisions of Section 3.4 of the Agreement.
- 1.2 Compensation to Physician and Group Provider for Excluded Services. When Physician and Group Provider is compensated on a Capitation Compensation basis, Physician or Group Provider shall accept as payment in full for Excluded Services the lesser of Physician's or Group Provider's usual and customary charge for the Covered Medical Services rendered to Members or AmCare's fee for service fee schedule, as amended from time to time, as payment in full, less the Copayments that Physician or Group Provider is entitled to collect from Members under the applicable Benefit Program.
- 1.3 Fee-for-Service Compensation to Physician and Group Provider for Contracted Services; Contracted Services Reciprocity. When Physician and Group Provider is not compensated on a Capitation Compensation basis or when a Member not under a Capitation Compensation arrangement receives Contracted Services from Physician or Group Provider, Physician or Group Provider shall accept as payment in full for Contracted Services the lesser of Physician's or Group Provider's usual and customary charge for the Covered Medical Services rendered to Members or AmCare's fee for service fee schedule as set forth in Exhibit 1 to this Addendum A and as amended from time to time, as payment in full, less the Copayments that Physician or Group Provider is entitled to collect from Members under the applicable Benefit Program.

HCPCS codes will be reimbursed at AWP + 10%. *(initials)*

TCC 000369

**EXHIBIT V / SCHEDULE 1**  
**Southwest Physician Associates**

**Provider Maximum Fee Schedule:**

This Beech Street fee schedule represents the payment due to Provider for providing Covered Services to Eligible Persons. Provider represents that this fee schedule is a discount from Provider's usual and customary charge in effect as of the date of service.

**Health Benefits/ Auto Medical— Physician Reimbursement Fee Schedule for:**

State: Texas Fee Zone: 71

RBRVS MULTIPLE: 160 % of 2001 (Dallas County Participating, Non Facility)

Anesthesia reimbursement is based on ASA and computed at 4 units per hour, \$ 57.00 per unit.

For codes that do not have a unit value assigned by RBRVS, St. Anthony's 2001 (year) Gap Fill will be used.  
For codes not included in either of the above, reimbursement will be at 20 % off billed charges.

Drugs and biologicals (J Codes) are reimbursed at the lesser of billed charges or 100% of AWP (Average Wholesale Price). Per Red Book current version.

All billings are subject to Beech Street Billing Guidelines. See Provider Manual for more information. (Provider Manual can be accessed on [www.beechstreet.com](http://www.beechstreet.com).)

Complete Fee Schedule will be furnished to Provider Group.

**Workers' Compensation**

Declined Participation.

**In no event would the fee schedule exceed the billed charges.**

SPH 002025

Albert Malcolm MD

**PHYSICIAN  
SERVICES AND COMPENSATION SCHEDULE**

**SERVICES:****COMPENSATION:**

Description:	Code:	Rate:
All J-codes	J0130-J9600	100% of AWP

For procedures and/or services not specifically listed, Provider agrees to accept as payment in full 122% of AETNA MARKET FEE SCHEDULE (AMFS).

Average Wholesale Pricing (AWP) for J-codes will be updated at a minimum of once annually.

Company utilizes the nationally recognized coding structure known as the AMA Current Procedural Terminology (CPT-4) for the basic coding, description of services and rules for the services provided. As annual changes are made to the CPT-4 codes, Company will update the coding structure, but the procedure remains materially the same.

CPT-4 codes included in the Professional Component of this Agreement apply to the services rendered and are not limited to the specialty of the performing provider.

Rates are inclusive of any applicable member copayment, coinsurance or deductible.  
Provider must designate the above codes when billing.

**Attachment M: Intron A HCPCS Crosswalk Information**

**Attachment M****July 2005 NDC - HCPCS Crosswalk for Medicare Part B Drugs****Effective July 1, 2005 through September 30, 2005****Note 1:** This crosswalk is based on published drug and biological pricing data and information submitted to CMS by manufacturers.**Note 2:** Please submit comments on the crosswalk to e-mail address: sec303aspdata@cms.hhs.gov.

HCPCS Code	Short Descriptor	Code Dosage Descriptor	Labeler Name	11-Digit National Drug Code (NDC)	Drug Name	Package Size	Package Quantity	Billable Units Per Package	Billable Units Per Package	Billable Units Per 11-Digit NDC
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-0539-01	Intron-A	1	1	50	50	50
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-0571-02	Intron-A	1	1	10	10	10
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1110-01	Intron-A	1	1	18	18	18
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1133-01	Intron-A	2.5	1	25	25	25
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1168-01	Intron-A	3	1	18	18	18
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1179-02	Intron-A	1	6	10	60	60
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1235-01	Intron-A	1.5	1	30	30	30
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1242-01	Intron-A	1.5	1	18	18	18
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1254-01	Intron-A	1.5	1	60	60	60

Source: <http://www.cms.hhs.gov>.

**Attachment M****April 2005 NDC - HCPCS Crosswalk for Medicare Part B Drugs****Effective April 1, 2005 through June 30, 2005****Note 1:** This crosswalk is based on published drug and biological pricing data.**Note 2:** Please submit comments on the crosswalk to e-mail address: sec303aspdata@cms.hhs.gov.

HCPCS Code	Short Descriptor	Code Dosage Descriptor	Labeler Name	11-Digit National Drug Code (NDC) Name	Drug Name	Package Size	Package Quantity	Billable Units Per Package	Billable Units Per Package	11-Digit NDC
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-0539-01	Intron-A	1	1	50	50	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-0571-02	Intron-A	1	1	10	10	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1110-01	Intron-A	1	1	18	18	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1133-01	Intron-A	2.5	1	25	25	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1168-01	Intron-A	3	1	18	18	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1179-02	Intron-A	1	6	10	60	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1235-01	Intron-A	1.5	1	30	30	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1242-01	Intron-A	1.5	1	18	18	
J9214	Interferon alfa-2b inj	1 MIL UNITS	SCHERING	00085-1254-01	Intron-A	1.5	1	60	60	
J9214	Interferon alfa-2b inj	1 MIL UNITS	PHYSICIANS TOTAL CARE	54868-3085-01	Intron-A	1	6	3	18	
J9214	Interferon alfa-2b inj	1 MIL UNITS	PHYSICIANS TOTAL CARE	54868-3341-00	Intron-A	1	1	50	50	

Source: <http://www.cms.hhs.gov>.

**Attachment M**

**October 2003 NDC - HCPCS Crosswalk for Medicare Part B Drugs**

HRN_NDC	HPCPS	NDC	HCPCS Description	Source	Version	Allowance Basis	Effective Date	Product Manufacturer	Brand Name	Package Description	Strength	Package Size	HCPCS Units/Pkg.	Unit of Measure	AWP Effective Date
00085-0539-01	J9214	00085-0539-01	Interferon alfa-2B, recombinant, 1 million units	MICROMEDEX Secure Downloads - Red Book	06/01/03	Brand - Intron A	10/01/03	Schering	Intron A	w/Diluent in Vial	50 Million IU	1s	50	1 million units	03/13/03
00085-0571-02	J9214	00085-0571-02	Interferon alfa-2B, recombinant, 1 million units	MICROMEDEX Secure Downloads - Red Book	06/01/03	Brand - Intron A	10/01/03	Schering	Intron A	w/Diluent in Vial	10 Million IU	1s	10	1 million units	03/13/03
00085-1110-01	J9214	00085-1110-01	Interferon alfa-2B, recombinant, 1 million units	MICROMEDEX Secure Downloads - Red Book	06/01/03	Brand - Intron A	10/01/03	Schering	Intron A	w/Diluent in Vial	18 Million IU	1s	18	1 million units	03/13/03

Source: <http://www.cms.hhs.gov>.